EXHIBIT 2

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1 IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY 2 CAMDEN VICINAGE 3 ***********************************	age 287 1 APPEARANCES (Continued): 2 3 GREENBERG TRAURIG LLP BY: KATE M. WITTLAKE, ESQ. 4 4 Embarcadero Center, Suite 3000 San Francisco, California 94111 5 415-655-1285 wittlakek@gtlaw.com 6 Representing the Defendants Teva Pharmaceutical Industries, Ltd., Teva 7 Pharmaceuticals SA, Inc., Actavis LLC, and Actavis Pharma, Inc.: 8 9 DUANE MORRIS, LLP BY: NATHAN B, REFDER, ESQ.	Page 289
deps@golkow.com	22 23	
24	24	
Part APPEARANCES: ALL PARTIES APPEARED REMOTELY MAZIE SLATER KATZ & FREEMAN, LLC BY: ADAM SLATER, ESQ. BY: CHERYLL A. CALDERON, ESQ. BY: CHERYLL A. CALDERON, ESQ. BY: CHRISTOPHER GEDDIS, ESQ. 103 Eisenhower Parkway Roseland, New Jersey 07068 973-228-9898 aslater@mazieslater.com ccalderon@mazieslater.com Representing the Plaintiffs HOLLIS LAW FIRM BY: IRIS SIMPSON, ESQ. BY: C. BRETT VAUGHN, ESQ. 8101 College Boulevard, Suite 260 College Boulevard, Suite 260 MORGAN & MORGAN BY: STEPHANIE JACKSON, ESQ. Negresenting the Plaintiffs MORGAN & MORGAN BY: STEPHANIE JACKSON, ESQ. North Orange Avenue, Suite 1600 Collando, Florida 32801 Sjackson@forthepeople.com Representing the Plaintiffs Representing the Plaintiffs FLEMING NOLAN JEZ, LLP BY: DAVID HOBBS, ESQ. 20 2800 Post Oak Boulevard Houston, Texas 77056 1 713-621-7944 david_hobbs@fleming-law.com Representing the Plaintiffs	DUANE MORRIS, LLP 3 BY: FREDERICK R. BALL, ESQ. 100 High Street 4 Boston, Massachusetts 02110 857-488-4229 5 Ifball@duanemorris.com Representing the Defendants Zhejiang 6 Huahai Pharmaceutical Co., Ltd., Prinston Pharmaceutical Inc., Huahai 7 U.S., Inc., and Solco Healthcare US, LLC 8 9 CIPRIANI & WERNER, P.C. BY: JULIA H. FERTEL, ESQ. 10 450 Sentry Parkway Blue Bell, Pennsylvania 19422 11 610-567-0700 jfertel@c-wlaw.com 12 Representing the Defendant Aurobindo Pharmaceuticals 13 14 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP 15 BY: FRANK STOY, ESQ. One Oxford Centre 16 Pittsburgh, Pennsylvania 15219 412-263-1840 17 fhs@pietragallo.com Representing the Defendant Mylan 18 Pharmaceuticals, Inc. 19 20 Also Present: Phil Hughes 21 Videographer: Judy Diaz 22 23 24	Page 290

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1	PROCEEDINGS	1	Genotoxic and Carcinogenic Impurities in Drug
2		2	Substances and Products: Recommended
3	THE VIDEOGRAPHER: We're now on	3	Approaches," and it's dated December 2008.
4	the record.	4	Do you see the document in
5	My name is Judy Diaz. I am the	5	front of you?
1			•
6	legal videographer for Golkow	6	A. Yes.
7	Litigation Services.	7	Q. And that's a document you're
8	Today's date is April 21, 2021,	8	familiar with, correct?
9	and the time is 7:05 a.m.	9	A. I, you know, read it before.
10	This remote video deposition is	10	MR. SLATER: Cheryll, let's
11	being held in the matter of Valsartan,	11	turn, if we could, to page 7, please.
12	Losartan, and Irbesartan Products	12	Great.
13	Liability Litigation MDL.	13	Q. Looking under heading IV,
14	This is the continuation of the	14	Section A is titled "Prevention of Genotoxic
15	deponent Min Li, Ph.D.	15	and Carcinogenic Impurity Formation."
16	All parties to this deposition	16	And it says, "Since
17	are appearing remotely and have agreed	17	drug-related impurities presumably provide
18	to the witness being sworn in	18	limited, if any, therapeutic benefits and
19	remotely.	19	·
	•		because of their potential to cause cancer in
20	All counsel will be noted on	20	humans, every feasible technical effort
21	the stenographic record.	21	should be made to prevent the formation of
22	And the court reporter is	22	genotoxic or carcinogenic compounds during
23	Maureen Pollard.	23	drug substance synthesis or drug product
24	///	24	manufacturing."
			3
	Page 296		Page 298
1	Page 296 MIN LI, Ph.D.,	1	Page 298
1	MIN LI, Ph.D.,	1 -	Page 298 And my question first is, NDMA
1 2	MIN LI, Ph.D., having been previously duly remotely sworn,	2	Page 298 And my question first is, NDMA and NDEA were drug-related impurities with
1 2 3	MIN LI, Ph.D., having been previously duly remotely sworn, was examined and testified further as	2 3	Page 298 And my question first is, NDMA and NDEA were drug-related impurities with regard to valsartan, correct?
1 2 3 4	MIN LI, Ph.D., having been previously duly remotely sworn, was examined and testified further as follows:	2 3 4	Page 298 And my question first is, NDMA and NDEA were drug-related impurities with regard to valsartan, correct? A. Yes.
1 2 3 4 5	MIN LI, Ph.D., having been previously duly remotely sworn, was examined and testified further as follows: FURTHER EXAMINATION	2 3 4 5	Page 298 And my question first is, NDMA and NDEA were drug-related impurities with regard to valsartan, correct? A. Yes. Q. And rephrase.
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	PageiD	<u>: 82</u>	119
	Page 299		Page 301
1	said, it's best to be answered by	1	The presence of NDMA and NDEA
2	toxicologists.	2	in ZHP's valsartan created a risk; it created
3	Q. Well, one of the topics here is	3	no benefit, correct?
4	"ZHP's evaluation and knowledge of the health	ի 4	MR. BALL: Objection.
5	risks of the nitrosamines, including NDMA and	5	Compound.
6	NDEA, including but not limited to as a	6	A. It's a potential risk.
7	contaminant of ZHP's valsartan API and ZHP's	s 7	BY MR. SLATER:
8	valsartan finished dose."	8	Q. Certainly having NDMA or NDEA
9	You do understand that's one of	9	in ZHP's valsartan increased the risk for a
10	the topics, correct?	10	person taking those pills to develop cancer.
11	A. Mm-hmm.	11	That's why it's called a probable carcinogen,
12	Q. In that context, I'm asking	12	correct?
13	you, are you saying there was some health	13	MR. BALL: Objection. Calls
14	benefit to having NDMA and NDEA in	14	for expert testimony, compound.
15	A. No, I'm not saying that.	15	A. Again, I'm not the best person,
16	Q the valsartan?	16	you know, to ask this question. A
17	A. I'm not saying that. As I	17	toxicologist would be much more appropriate.
18	said, you know, based upon up-to-date	18	BY MR. SLATER:
19	knowledge, it probably does not have, okay.	19	Q. Based on your preparation for
20	But the ultimate answer is best to be	20	the deposition, your review of all the
21	answered by, you know, toxicologists.	21	materials you reviewed, you would agree with
22	Q. As you sit here now, there's no	22	me that the presence of the NDMA and NDEA in
23	benefit at all that you can point to of NDMA	23	the valsartan created some level of increased
24	or NDEA being in ZHP's valsartan, right?		
	of NDLA being in Zi if 5 valsarian, fight:	24	risk for cancer for people who took those
	Page 300		Page 302
1	Page 300 A. As I already said, you know, up	1	Page 302 pills, correct?
1 2	A. As I already said, you know, up to this point, it does not have any	1 2	pills, correct? A. Again
1 2 3	A. As I already said, you know, up to this point, it does not have any information to show that, as far as I know.	1 2 3	pills, correct? A. Again MR. BALL: Objection. Calls
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1	that's the same question that you already	1	it.
2	asked, you know, quite a few times.	2	MR. BALL: I'm not every time
3	BY MR. SLATER:	3	you ask a question on this topic. I'm
4	Q. Is the answer yes, that to some	4	going to ask the ones that actually
5	extent there's an increased risk of cancer?	5	call for expert testimony as opposed
6	 As I told you, I'm not the best 	6	to ZHP's evaluation and knowledge of
7	person to give an answer on that.	7	the health risks of nitrosamines.
8	Q. Well, that is one of the topics	8	If you want to ask questions
9	that you were designated to testify on.	9	about that as opposed to trying to put
10	And with due respect to my	10	words in his mouth, that's fine, but
11	esteemed colleague Mr. Ball, I don't think	11	that's not what you're doing.
12	it's expert testimony, because it's a	12	BY MR. SLATER:
13	Court-ordered designation topic for a	13	Q. The presence of the NDMA in the
14	corporate representative to answer questions	14	valsartan created a health risk, correct?
15	on this. So that's why I'm trying to ask the	15	A. I think yesterday, you know, I
16	question.	16	already answered this question, you know,
17	MR. BALL: Hold on for a	17	because according to today's knowledge or
18	second.	18	whatever the information given by, for
19	We can stay on the record and	19	example, like FDA's, right, it's not any
20	discuss this, or we can go off the	20	level, you know, of the presence will give
21	record and discuss it. Which would	21	the potential risk. It there is a
22	you prefer to do?	22	threshold as of today, okay.
23	MR. SLATER: I don't need to	23	As I said yesterday, you know,
24	discuss it. I just wanted to I'm	24	the daily allowable intake defined by FDA is
	Page 304		Page 306
1	happy to	1	96 nanogram per day.
2	MR. BALL: Then I'm going to	2	Q. The NDMA levels in ZHP's
3	continue my objections, and he can	3	valsartan were higher in every single batch
4	answer to the degree he can.	4	that was tested than 96 nanograms, correct?
5	MR. SLATER: Well, I will	5	MR. BALL: Objection.
6	MR. BALL: You can ask him if	6	Foundation.
7	there were evaluation and knowledge	7	A. As I indicated, you know, this
8	related to	8	is not correct because you really have to
9	MR. SLATER: I'm not going to	9	differentiate, you know, the valsartan
10	have	10	product from which processes. Okay. From
11	MR. BALL: You mean I	11	the TEA processes, as far as I know, the vast
12	offered to go off the record, Adam.	12	majority of them, you know, the tested were
13	MR. SLATER: You don't know	13	below the 96 nanogram per day.
14	what I'm going to say.	14	BY MR. SLATER:
15	MR. BALL: You said you didn't	15	Q. Let's talk about the zinc
16	want to.	16	chloride process for a moment. Every single
	want to.		
17	MR. SLATER: Rick, relax, you	17	batch manufactured with the zinc chloride
			batch manufactured with the zinc chloride process exceeded the FDA limit of
17	MR. SLATER: Rick, relax, you	17	
17 18	MR. SLATER: Rick, relax, you don't know what I'm going to say.	17 18	process exceeded the FDA limit of
17 18 19	MR. SLATER: Rick, relax, you don't know what I'm going to say. I'm going to give you a	17 18 19	process exceeded the FDA limit of 96 nanograms, correct?
17 18 19 20	MR. SLATER: Rick, relax, you don't know what I'm going to say. I'm going to give you a standing objection to every time I ask	17 18 19 20	process exceeded the FDA limit of 96 nanograms, correct? MR. BALL: Objection.
17 18 19 20 21	MR. SLATER: Rick, relax, you don't know what I'm going to say. I'm going to give you a standing objection to every time I ask a question under this topic that	17 18 19 20 21	process exceeded the FDA limit of 96 nanograms, correct? MR. BALL: Objection. Foundation.
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Page 307 1 BY MR. SLATER: 2 Q. And for every single one of 3 those valsartan pills that was made with that 4 API with the zinc chloride process, there was 5 a health risk for those patients that used 6 those pills, correct? 7 MR. BALL: Objection. 8 Foundation. Asks for calls for 9 expert testimony. 10 A. Well, I think the correct 11 answer or the statement or description would 12 be potential risk. 13 BY MR. SLATER: 15 night "consensus." The scientific consensus, 16 the majority of scientists who know who 17 are looking at this issue would agree that 18 there was an increased risk for those 19 patients who used the zinc chloride valsartan 10 manufactured by ZHP, they rephrase. Let 11 me ask it again. 12 The consensus is that using the 12 valsartan that was manufactured with the zinc 13 but you'd agree there was some increase as 4 result of taking those pills, correct? 2 MR. BALL: Objection. 24 Chloride process increased those patients' 25 MR. BALL: Objection. 26 Speculative, vague, and calls for 27 expert testimony. 28 A. Again, the risk is potential 29 risk. 20 Whatever studies it may be 21 be the read of this patients with the zinc 22 chloride process increased those patients' 26 MR. BALL: Objection. 27 Valsartan that was manufactured with the zinc 28 valsartan that was manufactured with the zinc 29 valsartan that was manufactured with the zinc 20 chloride process increased those patients' 21 risk. 22 By MR. SLATER: 23 Universe the value of the patient would knowingly ever accept if they 25 had they save to be evaluated on an 26 that they have to be evaluated on an 27 item-by-item basis, correct? 28 MR. BALL: Objection. Calls 29 for expert testimony, vague. 30 A. I need to point out that here, 31 by know, the wording here, high carcinogenic, 40 Chloride process is that using the 41 be valued from the threshold approach is 41 textuded from the threshold approach is 42 because they're considered to be so dangerous 42 that they have to be evaluated on an 43 titem-by-item basis, correct? 40 A. I need to
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9 risk. 10 MR. SLATER: Please go, 11 Cheryll, to page 8, if you could. The 11 need to take, they need to ask or consult
10 MR. SLATER: Please go, 10 A. Whatever medicine a patient 11 Cheryll, to page 8, if you could. The 11 need to take, they need to ask or consult
11 Cheryll, to page 8, if you could. The 11 need to take, they need to ask or consult
12
13 BY MR. SLATER: 13 BY MR. SLATER:
14 Q. At the top of page 8 there's 14 Q. Well, ZHP understands that the
discussion about the threshold approach, and 15 reason that the worldwide regulatory
16 it says in the last sentence, "However, there 16 authorities required ZHP to stop selling its
17 are some compounds containing certain 17 valsartan was because the risk to patients of
18 structural groups (aflatoxin-like, 18 developing cancer due to the nitrosamine
19 N-nitroso-, and azoxy-structures) that have 19 contamination was considered to be too great
20 extremely high carcinogenic potency and are 20 You understand that, right?
21 excluded from the threshold approach." 21 MR. BALL: Objection.
You understand that, correct? 22 Speculative.
laa
23 A. Yes. 23 A. I think yesterday, yes, sir, I

PageID: 82122 Page 311 Page 313 1 And also as I mentioned yesterday, you know, recall the pills, correct? 2 MR. BALL: Objection. 2 once we have complete our very intense, you 3 Compound, and mischaracterizes his 3 know, investigation, like it was in like two, 4 three weeks, you know, once we have, you 4 testimony. 5 5 know, a -- you know, good numbers of, you Α. Yeah, that's basically what I 6 know, of the value of the NDMA, we 6 said. Yeah. 7 BY MR. SLATER: 7 immediately contact FDA as well as, you know, 8 other regulatory agencies. Okay. We ask FDA 8 Q. ZHP did not do that as of July 9 for, you know, guidance, right. We ask them 9 2017, correct? That I need to go to, I think, 10 whether we should immediately do the recall. 10 A. one of the documents. We have the timetable 11 And as I mentioned yesterday, 11 of, you know, chronology of all the events. 12 the answer, or at least the initial answer 12 13 I don't remember all the details. 13 from the FDA, they ask us to hold on upon But basically the thing is, as 14 further notifications. Okay, so this is 14 15 exactly what happened. 15 I said, once we complete our initial 16 investigations, okay, and we just, you know, 16 BY MR. SLATER: 17 quickly contact FDA. And I think between the 17 Q. Let's go through a few of the initial contact and the FDA's next, you know, 18 things you just said. 18 19 Number one, you're saying ZHP 19 actions, there -- the time was at least about made the decision to voluntarily recall the 20 a week or maybe even longer, okay. 20 21 valsartan contaminated with nitrosamines. 21 I think maybe you misheard my 22 Did I understand you correctly? 22 question. I'll ask it again. As of July 27, 2017 --23 A. As I said, we contacted -- once 23 24 24 we, you know, have the results or the initial Oh, I'm sorry. 2000 -- well, Α. Page 312 Page 314 results, we contacted FDA, okay, asking as I said, as a company as a whole, you know, 2 whether we just should go ahead with the 2 we didn't know that. 3 recall. 3 Q. People within your company knew 4 Q. You understood that a recall 4 this, correct? 5 was likely the appropriate next step after 5 MR. BALL: Objection. Vague, you confirmed the nitrosamine contamination 6 speculative. 7 of your valsartan, and that's why you asked 7 BY MR. SLATER: 8 that question of the FDA, is that what you're 8 All right. I'll ask the saying? 9 9 question again. Stop for a second, Dr. Li, 10 MR. BALL: Objection. Outside I'll ask the question again. 11 As of July 27, 2017, there were the scope. 11 Go ahead and answer, Dr. Li. 12 12 people in your company who were on notice, 13 Because there was a potential including you, that the valsartan Α. 13 risk, right, so as a responsible company, you manufactured with the zinc chloride process 15 know, once you confirm the initial results, 15 was contaminated with NDMA, correct? 16 you know, have reliable results, you know, to 16 A. No, that's not true. As I 17 your best knowledge, you know, this is a indicated yesterday, you know, based upon, 17 18 response the company should do, so that's you know, the content, you know, of that 19 what ZHP did. particular exhibit, you know, it looks like 19 20 BY MR. SLATER: he was making his speculations. 20 21 As soon as ZHP knew that its 21 Whatever you want to call it, 22 valsartan was contaminated with NDMA, the 22 speculations, he was correct and that was

23

24

confirmed for the worldwide regulatory

authorities, including the FDA, right, that

23

responsible thing to do, as you just said,

24 was to contact the FDA and take steps to

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	Page 315	02	Page 317
1	NDMA was in the valsartan that your company	1	and heart attacks because they don't have the
2	was selling, right?	2	blood pressure pills over the next week.
3	MR. BALL: Objection. Vague	3	You understood that's what the
4	and compound.	4	FDA was evaluating, right?
5	A. That was after, you know, the	5	MR. BALL: Objection.
6	company become aware, after, you know, the	6	Speculation, calls for expert
7	June 6, 2018.	7	testimony, compound, and I think every
8	BY MR. SLATER:	8	other objection to form I could think.
9	Q. Well, it was after ZHP realized	9	A. Yeah, I don't know exactly what
10	that if it didn't tell the FDA about the	10	FDA was thinking at the time.
11	contamination with NDMA, that Novartis was	11	BY MR. SLATER:
12	probably going to do so, so ZHP had no choice	12	Q. Well, you're talking about what
13	at that point, right?	13	the FDA you affirmatively rephrase.
14	MR. BALL: Objection.	14	You're the one who brought up
15	Speculative and compound.	15	what the FDA told you or didn't tell you, so
16	A. That's your speculation.	16	that's why I'm asking what those discussions
17	That's not, you know, what I felt.	17	were.
18	BY MR. SLATER:	18	You apparently know about them,
19	Q. Let's go back to my original	19	right?
20	question.	20	A. They didn't tell us the reason.
21	In July of 2017, ZHP did not	21	They just said hold on.
22	notify the FDA that there was NDMA in the	22	Q. Shortly after ZHP notified the
23	zinc chloride process manufactured valsartan,	23	FDA about the NDMA in ZHP's valsartan, ZH
24	correct?	24	stopped selling the valsartan and recalled
	Page 316		Page 318
1	A. As I told you, you know, the	1	it, correct?
2	company did not know at the time.	2	MR. BALL: Objection.
3	Q. I'm not well, my question is	3	Compound.
4	whether or not the company notified the FDA	4	A. I'm sorry. Say that again,
5	at that time.	5	please?
6	MR. BALL: Dr. Li, that's a	6	BY MR. SLATER:
7	yes-or-no question. To the degree you	7	Q. Sure.
8	can answer yes or no, please answer	8	Shortly after ZHP notified the
9	yes or no.	9	FDA that there was NDMA in the valsartan,
10	 A. Well, because the company did 	10	within a short period of time after that, ZHP
11	not know, so the answer is no.	11	stopped selling that valsartan and recalled
12	BY MR. SLATER:	12	it in the United States and worldwide,
13	Q. You said earlier that the FDA	13	correct?
14	told ZHP not to recall the valsartan	14	MR. BALL: Objection. Vague,
15	immediately, or something to that effect,	15	compound.
16	correct?	16	A. I think I would really need to,
17	A. Something like that, yes.	17	you know, take a look at that particular
18	Q. And that was because the FDA	18	timetable, you know, describing, you know,
19	first needed to ensure that there was	19	like which events happened.
100	and the state of t	100	Many longers of maladate consequents to

22

24

22 market, because as bad as it was to have an 23 increased risk of cancer over time, it could

24 be worse for people to start having strokes

20 adequate supply of blood pressure pills

21 before these pills would be pulled off the

You know, it might -- we might

production, you know, or it may, you know,

But as I said, we have that

21 already, you know, like have stopped the

23 happen almost at the same time.

PageID: 82124 Page 319 Page 321 1 document. So I think the best way is just, 1 Again, you know, as I said, you know, you know, the best answer would be by a 2 you know, you know, you can upload that 3 document. I mean, let's take a look, you toxicologist in terms of what level, you 4 know, what exactly, you know, going to happen know, is acceptable, what level is not 5 every step. 5 acceptable. 6 BY MR. SLATER: 6 BY MR. SLATER: 7 Q. The reason that ZHP, as you 7 Q. I am asking you the questions said, made the decision to recall and stop 8 because you were designated by ZHP to testify 8 selling its contaminated valsartan was on this topic, so you're the person I have to 9 9 10 because ZHP deemed the health risk to ask the questions. 10 patients to be unacceptable, correct? 11 MR. BALL: That's not what 11 12 MR. BALL: Objection. Vague 12 you're asking him, Adam. You're asking him things that are outside 13 and compound. 13 Again, I said it's a potential the -- you're asking for expert 14 Α. 14 testimony, you're not asking for 15 risk. 15 BY MR. SLATER: factual testimony, and you're putting 16 16 17 And it's a potential risk 17 words in his mouth. 18 that's unacceptable -- rephrase. 18 So feel free to ask him 19 And it was a potential risk 19 questions which were within the topic. 20 that was unacceptable for patients, correct? I'm happy to have you do that. 20 MR. BALL: Objection. Vague, 21 MR. SLATER: Cheryll, let's go 21 22 and calls for expert testimony. 22 now to a new exhibit. Let's go to 23 Again, it's a potential risk to 23 Exhibit 206, please. Thank you. A. 24 /// 24 patient. Page 320 Page 322 BY MR. SLATER: BY MR. SLATER: 1 2 2 On the screen is Exhibit 206, An unacceptable potential risk. That's why ZHP stopped selling valsartan and 3 which is the June 28, 2006 European Medicines 3 Agency Guidelines on the Limits of Genotoxic 4 recalled it, correct? Impurities, which was valid from January 1, MR. BALL: Objection. Vague, 5 5 mischaracterizes his prior testimony, 2007 to January 31, 2018. 6 7 and foundation. 7 Do you see that? So according -- you know, 8 Mm-hmm. 8 Α.

- basically once we knew, you know, the
- presence of NDMA, and, you know, once we knew
- 11 potentially, okay, to the patient, we -- you
- know, as I said, after we confirmed the 12
- 13 results, okay, you know, we stopped the
- 14 production and distribution, and also
- 15 contact, you know, regulatory agencies.
- BY MR. SLATER: 16
- And that's because ZHP knew 17
- 18 that the potential risk to patients of taking
- 19 those pills was an unacceptable health risk,
- 20 correct?
- 21 MR. BALL: Objection. Vague,
- calls for expert testimony, and 22
- 23 mischaracterizes his earlier
- 24 testimony.

- MR. SLATER: Cheryll, let's go, 9
- 10 if we could, to page 4 of 8 at the
- top, the section titled "Toxicological 11
- 12 Background," please.
 - THE WITNESS: Could you make it
- 14 a little bigger, please? Yes. Thank
- you. 15

13

- 16 BY MR. SLATER:
- 17 Section 4 of this document from
- 18 the European Medicines Agency is titled
- "Toxicological Background," and it states, 19
- "According to current regulatory practice it 20
- 21 is assumed that (in vivo) genotoxic compounds
- 22 have the potential to damage DNA at any level
- of exposure and that such damage may 23
- 24 lead/contribute to tumour development. Thus

PageID: 82125 Page 323 Page 325 1 for genotoxic carcinogens it is prudent to description here, it was derived from animal 2 assume that there is no discernible threshold studies. And also, I'm not sure, you know, and that any level of exposure carries a you know, the current, you know, M7, whatever 4 risk." 4 the exactly same, you know, opinion, you 5 Do you see that? 5 know, you know, on this. I think in M7 it 6 A. Yes. probably has an acceptable levels. So maybe 7 Q. NDMA is a genotoxic compound as that's why the reason, you know, you know, discussed here, correct? 8 this document become obsolete. 9 Α. Yes. 9 BY MR. SLATER: Q. NDEA is a genotoxic compound as 10 10 Q. I'll try it again. discussed here, correct? 11 11 When this refers to geno- --MR. BALL: Objection. Vague. 12 12 rephrase. A. 13 Yes. 13 When this refers to genotoxic BY MR. SLATER: 14 compounds have the potential to damage DNA at 15 And when they talk about the Q. any level of exposure, that's talking about potential to damage DNA at any level of 16 these genotoxic compounds being mutagenic, exposure, they're talking about these being 17 that's what that means, correct? 17 mutagenic genotoxic compounds, correct? 18 18 What I understand --MR. BALL: Objection. 19 19 MR. BALL: Objection --20 Speculative and vague, calls for 20 THE WITNESS: Go ahead. 21 expert testimony. 21 MR. BALL: Objection. 22 Go ahead and answer. 22 Speculative, calls for expert To the animals. These results 23 Α. 23 testimony. 24 all derived from animal studies. To the degree you can answer 24 Page 324 Page 326 BY MR. SLATER: 1 1 under your understanding, go ahead, 2 Your understanding is that this 2 Doctor. 3 standard was written to determine whether or Α. Right. Yeah. So based upon to what extent genotoxic compounds would be what I understand, all of these data are given to animals? 5 results from animal studies, and it was very MR. BALL: Objection to form. 6 high, you know, doses. 7 Dr. Li, please let me get my 7 BY MR. SLATER: 8 objection in. 8 Did I ask you what the basis Mischaracterizes his earlier 9 for this statement was in this EMA guidance 10 testimony. document in terms of what type of studies 11 Well, basically all of those 11 this was based on? results, okay, based upon, you know, you 12 12 Α. From some of the other know, documents like this, they all derived documents, I don't, you know, remember, like, 14 from animal studies at very high dosage. you know, either like M7 or some other --BY MR. SLATER: 15 FDA's document or EMA's document, or if you 16 Q. Okay. Coming back to the 16 can go to the literature, you know, all of 17 question I asked you, when this refers to the 17 those data with nitrosamine, they were potential to damage DNA at any level of 18 derived from animal studies, as far as I 19 exposure, that's talking about it being a 19 know. mutagenic, genotoxic compound, correct? 20 20 The reference to genotoxic MR. BALL: Objection. 21 21 compounds have the potential to damage DNA at Speculative. 22 22 any level of exposure is a reference to As I said, that the potential 23 23 mutagenic/genotoxic compounds. That's what 24 risk here or understanding of whatever the mutagenic means, right?

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1	MR. BALL: Objection.	1	correct?
2	Compound, calls for expert testimony,	2	A. Yeah, at very high doses.
3	speculative, and foundation.	3	 Q. This document from the European
4	A. Again, as I said, you know,	4	Medicines Agency states in the sentence we
5	basically this statement, based upon my	5	just went over, "Thus for genotoxic
6	understanding, okay, this statement was based	6	carcinogens it is prudent to assume that
7	upon animal studies, okay, with very high	7	there is no discernible threshold and that
8	doses.	8	any level of exposure carries a risk."
9	MR. BALL: Adam, he's clearly	9	That's a true statement,
10	not understanding the question. Maybe	10	correct? ZHP agrees with that statement,
11	if you ask it in a different way.	11	right?
12	MR. SLATER: This is a Ph.D	12	A. That is a statement in that
13	from Johns Hopkins.	13	document, yes, 2008.
14	MR. BALL: Okay. Adam, would	14	MR. SLATER: Let's go to
15	you like me to ask him a question?	15	page 6, please, Cheryll. Thank you.
16	MR. SLATER: No.	16	Scroll up a little bit. A little
17	MR. BALL: I want to okay.	17	more. Wonderful. Thank you.
18	I'm just trying to help you out,	18	Q. Looking at the center of the
19	buddy. I you know, I'm saying if	19	page, the first full paragraph, this EMA
20	you're going to say that he's a Ph.D,	20	document states, "Some structural groups were
21	I'm just suggesting he's clearly not	21	identified to be of such high potency that
22	understanding the question, because I	22	intakes even below the threshold of
23	kind of understand the question, but	23	toxicological concern would be associated
24	he is not.	24	with a high probability of a significant
			3 1111 3 1111
	B 000		B 000
1	Page 328	4	Page 330
1	MR. SLATER: That's okay. I'll	1	carcinogenic risk," and then there's
2	MR. SLATER: That's okay. I'll do I'm doing the best I can.	2	carcinogenic risk," and then there's citations to two articles, one from 1999 and
2 3	MR. SLATER: That's okay. I'll do I'm doing the best I can. MR. BALL: That's okay.	2	carcinogenic risk," and then there's citations to two articles, one from 1999 and one from 2004.
2 3 4	MR. SLATER: That's okay. I'll do I'm doing the best I can. MR. BALL: That's okay. MR. SLATER: But I would prefer	2 3 4	carcinogenic risk," and then there's citations to two articles, one from 1999 and one from 2004. Do you see that?
2 3 4 5	MR. SLATER: That's okay. I'll do I'm doing the best I can. MR. BALL: That's okay. MR. SLATER: But I would prefer that you not ask the questions.	2 3 4 5	carcinogenic risk," and then there's citations to two articles, one from 1999 and one from 2004. Do you see that? A. Yes.
2 3 4 5 6	MR. SLATER: That's okay. I'll do I'm doing the best I can. MR. BALL: That's okay. MR. SLATER: But I would prefer that you not ask the questions. MR. BALL: That's fine. I	2 3 4 5 6	carcinogenic risk," and then there's citations to two articles, one from 1999 and one from 2004. Do you see that? A. Yes. Q. A significant carcinogenic risk
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2 3 4 5 6 7 8	MR. SLATER: That's okay. I'll do I'm doing the best I can. MR. BALL: That's okay. MR. SLATER: But I would prefer that you not ask the questions. MR. BALL: That's fine. I won't, then. MR. SLATER: Thank you.	2 3 4 5 6 7 8	carcinogenic risk," and then there's citations to two articles, one from 1999 and one from 2004. Do you see that? A. Yes. Q. A significant carcinogenic risk would be a significant risk of developing cancer. That's what that phrase means,
2 3 4 5 6 7 8 9	MR. SLATER: That's okay. I'll do I'm doing the best I can. MR. BALL: That's okay. MR. SLATER: But I would prefer that you not ask the questions. MR. BALL: That's fine. I won't, then. MR. SLATER: Thank you. BY MR. SLATER:	2 3 4 5 6 7 8 9	carcinogenic risk," and then there's citations to two articles, one from 1999 and one from 2004. Do you see that? A. Yes. Q. A significant carcinogenic risk would be a significant risk of developing cancer. That's what that phrase means, correct?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. SLATER: That's okay. I'll do I'm doing the best I can. MR. BALL: That's okay. MR. SLATER: But I would prefer that you not ask the questions. MR. BALL: That's fine. I won't, then. MR. SLATER: Thank you. BY MR. SLATER: Q. What does the term "mutagenic" mean? A. Mutagenic, which means it cause mutation in genes. Q. Damage to someone's DNA, correct? MR. BALL: Objection. Vague. A. As I said here, you know, referring to this very statement here, okay, it's based upon animal study, okay. Animal study at the very high doses, okay, it shows mutagenic to animals.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	carcinogenic risk," and then there's citations to two articles, one from 1999 and one from 2004. Do you see that? A. Yes. Q. A significant carcinogenic risk would be a significant risk of developing cancer. That's what that phrase means, correct? MR. BALL: Objection. Foundation. A. It says a high probability. And again, although I haven't gone through these two papers, but based upon everything, you know, that I know, these results most likely derived from animal studies. BY MR. SLATER: Q. When this phrase rephrase. When this refers to a significant carcinogenic risk, that means by definition a significant risk of developing

Page 331 Page 333 1 foundation. and, you know, initiate the recall, you know, 2 It says, "a high probability of 2 everything. a significant carcinogenic risk." It's still 3 MR. SLATER: Cheryll, you a probability, although it's a high 4 switched the page for some reason. 5 probability. 5 Can you scroll up a little bit 6 Again, you know, this is from 6 again just to get that paragraph a 7 animal studies. little higher up on the page? Thank 7 8 BY MR. SLATER: 8 you. That's good. 9 A significant carcinogenic risk Q. 9 BY MR. SLATER: is a significant risk of developing cancer, 10 10 Q. It was not acceptable to sell 11 correct? 11 valsartan with NDMA contamination because of 12 MR. BALL: Objection. Vague, 12 the high probability of a significant 13 foundation. 13 carcinogenic risk, correct? 14 Α. No matter what, you know, it's 14 MR. BALL: Objection. 15 still a probability. 15 Mischaracterizes his earlier BY MR. SLATER: 16 16 testimony, calls for expert testimony. 17 Q. A carcinogenic risk is a risk 17 You know, as I told you, you 18 of developing cancer, correct? know, once, you know, once we knew, you know, 18 MR. BALL: Objection. Vague, 19 in June 2018 and once we determined, you 20 foundation, and calls for expert know, the levels, we immediately, you know, 21 testimony. 21 contacted regulatory agencies and take 22 Α. Well, based upon this wording, 22 actions. right, this specific wording, carcinogenic 23 23 BY MR. SLATER: risk, you're right, it is, you know, 24 24 Are you aware of studies that Page 332 Page 334 have been done concluding that it is probable 1 developing the risk for developing cancer. 2 But as I said here, if you look at the whole 2 that NDMA will cause cancer in humans? 3 sentence, okay, it says, "a high probability 3 A. I don't know, you know, what --4 of a significant carcinogenic risk." So it's which is specific like a paper or study, you 5 know, that you are referring to, I mean. 5 still a risk. Are you saying you're not 6 And again, you know, as I said, 6 familiar with anything in the scientific 7 these study most likely, you know, based upon literature at all that says that it's 8 animal studies. probable that NDMA will cause cancer in BY MR. SLATER: 9 9 Does ZHP think it is a good 10 humans? 10 11 MR. BALL: Objection. 11 idea to sell pills contaminated with a 12 Mischaracterizes his testimony. substance that carry with them a high probability of a significant carcinogenic 13 As I said, that, you know, 13 Α. basically as I said, you know, people making 14 risk? those hypothesis or whatever, based upon MR. BALL: Objection. 15 15 animal studies, okay. Argumentative, foundation. 16 16 As I told you, you know, as a 17 BY MR. SLATER: 17 18 company we didn't know until June 6, 2018. In preparing yourself to talk 18 Q. 19 about ZHP's evaluation and knowledge of the So, you know, the company will not knowingly, 19 you know, you know, to distribute the 20 health risks of nitrosamines, including NDMA and NDEA, including but not limited to as a 21 product. So that's why, as I say, once we contaminant of ZHP's valsartan API and ZHP's 22 22 knew, you know, at the company level and once 23 valsartan finished dose, did you review any 23 we determined, you know, the levels, okay, so 24 we did everything we can and contact agency 24 studies addressing risk to humans of

PageID: 82128 Page 335 Page 337 developing cancer due to exposure to NDMA? they seem to be all -- you know, all, like, 2 Yes, I did review some papers, related to animal. okay. There is one particular, you know, 3 3 There may be like, you know, 4 paper, you know, they came out after another one. They may be doing a similar 5 ranitidine, you know, NDMA issue was, you study, you know. But to me, you know, the know, was discovered, okay. study design, you know, may not be very well, 6 6 7 That paper from my own 7 you know, controlled. perspective, right, from a scientific design, 8 8 I mean, because whenever you do I think, you know, this is a very good study, 9 9 those things you -- from a scientific basis, 10 okay? This study was published by a group of you know, you need to well control, you know, 10 11 Korean, you know, medical doctors. Okay. 11 you know, your patient population. And also 12 In this particular, you know, 12 your patient population need to be large 13 retrospective review, right, they compared 13 enough to be statistically meaningful, right? 40,000 patients, or maybe 40-plus thousand, 14 So in this case, 40-plus 15 okay, patients taking ranitidine, okay. 15 thousand versus 10,000, you know, 10,000-plus Ranitidine by now, you know, 16 control group, you know, to me it's a very 17 people know it will -- you know, ranitidine well-controlled study. 17 18 will decompose, and also -- it will also, you 18 So you mentioned a study done know, you know, metabolize within human body, 19 out of Korea. Are you aware of any other 20 okay, to very high level of NDMA. studies addressing the risk of cancer to 20 I think yesterday I may have 21 21 humans due to nitrosamines?

Page 336

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per day, okay?

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And they compared, you know, 3 this group of patient with another group of patient, 10,000-plus patient, taking 4 5 another -- you know, same class, like an antacid, you know, drug which is called famotidine, okay.

know, you know, with a single person taking

150 milligram of ranitidine, was 47 microgram

22 mentioned, I think, an average level, you

Famotidine, it is known by now it will not, you know, decompose to give NDMA, or it will not, you know, be metabolized to give NDMA, right?

So they compared these two 13 group of people retrospectively. And the 14 conclusion from this, you know, very well, 15 you know, controlled study, they -- I think 16 the conclusion says there is no -- basically 17 there's no difference in terms of the cancer 18 risk between the two groups.

- Is that the only study you're Q. 20 aware of that's addressed this issue?
- That's the study that I just 22 came across most recently. The vast majority, you know, of the other paper, as 24 far as I, you know, came across, you know,

through them, you know.

But as I said, you know, over the course, you know, since June 2018, it seems to me, you know, the vast majority of the studies were based upon the animals.

There may be some, but I

haven't -- you know, due to my limited time,

I haven't, you know, had a chance to go

- Does ZHP have a collection of 6 literature regarding the risk to humans of 8 nitrosamine ingestion?
- 9 I don't know that there is like 10 a -- like a complete, like a compilation, but -- you know, but for myself during the 11 course of this preparation, I downloaded some 12 13 papers.
- 14 You've told us about a study 15 out of Korea. Is there any other study known to you or ZHP as you sit here now addressing 16 17 the risk to humans due to ingestion of 18 nitrosamines?
- There may be some others, but Α. as I said, you know, I haven't had a time, you know, you know, to go through them. So don't know the specifics, you know, the other ones. Maybe the other ones, you know, as I 24 said, I just came across.

LI. MIN Ph.D. 04/21/2021

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	Page 339		Page 341
1	But this particular one,	1	mentioned, you know, impurity K of valsartan,
2	because of, as I said, well designed, you	2	it has been treated as a regular impurity by
3	know, studies with large significant, you	3	the original innovator, Novartis.
4	know, you know, patient populations.	4	Q. In terms of the nitrosamines
5	Q. Coming back to the EMA	5	that are high potency genotoxic
6	standard, this indicates in the paragraph	6	carcinogenics, one of those is NDMA, right?
7	we've been reading on page 6, in the second	7	A. As I said, the NDMA or NDEA,
8	sentence, "This group of high potency	8	they have potentially high risk potential
9		9	high risk, based upon animal studies.
	genotoxic carcinogens comprises		•
10	aflatoxin-like, N-nitroso-, and	10	Q. That potential high risk is
11	azoxy-compounds that have to be excluded from	11	considered to be unacceptable in valsartan,
12	the threshold of toxicological concern	12	correct?
13	approach. Risk assessment of members of such	13	MR. BALL: Objection.
14	groups require compound-specific toxicity	14	Foundation, calls for expert
15	data."	15	testimony.
16	Do you see what I just read?	16	A. I think I answered, you know,
17	A. Yes.	17	this question before. You know, with regard
18	Q. And, again, when they	18	to, you know, acceptable level in patient, I
19	rephrase.	19	think it's best answered by a toxicologist.
20	When the EMA standards	20	BY MR. SLATER:
21	rephrase.	21	Q. In terms of what actually
22	When this EMA guidance document	22	happened in June of 2018, the consensus among
23	refers to N-nitroso-, they're talking about	23	those scientists responsible for this issue
24	nitrosamines including NDMA, correct?	24	in the United States was that this risk was
	_		
	Page 340		
1	Page 340 A. NDMA is one member of this	1	Page 342
	A. NDMA is one member of this	1 2	Page 342 unacceptable for patients, correct?
2	A. NDMA is one member of this class compound.	2	unacceptable for patients, correct? MR. BALL: Objection. Vague,
2 3	A. NDMA is one member of this class compound. Q. And another rephrase.	2 3	unacceptable for patients, correct? MR. BALL: Objection. Vague, calls for expert testimony, and
2 3 4	A. NDMA is one member of this class compound. Q. And another rephrase. Another nitroso compound is	2 3 4	unacceptable for patients, correct? MR. BALL: Objection. Vague, calls for expert testimony, and speculative.
2 3 4 5	A. NDMA is one member of this class compound. Q. And another rephrase. Another nitroso compound is NDEA, correct?	2 3 4 5	unacceptable for patients, correct? MR. BALL: Objection. Vague, calls for expert testimony, and speculative. A. I think this is the same
2 3 4 5 6	A. NDMA is one member of this class compound. Q. And another rephrase. Another nitroso compound is NDEA, correct? A. Yes.	2 3 4 5 6	unacceptable for patients, correct? MR. BALL: Objection. Vague, calls for expert testimony, and speculative. A. I think this is the same question you just asked before.
2 3 4 5 6 7	A. NDMA is one member of this class compound. Q. And another rephrase. Another nitroso compound is NDEA, correct? A. Yes. Q. And the European Regulatory	2 3 4 5 6 7	unacceptable for patients, correct? MR. BALL: Objection. Vague, calls for expert testimony, and speculative. A. I think this is the same question you just asked before. BY MR. SLATER:
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	Page 343		Page 345
1	thorough investigation is based upon the	1	you what we're going to next, or ask
2	potential risk.	2	you to take us to where we're going
3	BY MR. SLATER:	3	next.
4	Q. All risks are potential,	4	Okay. Let's go to ZHP01390339,
5	correct?	5	please.
6	MR. BALL: Objection. Vague.	6	(Whereupon, Exhibit Number
7	BY MR. SLATER:	7	ZHP-306was marked for
8	Q. That's why they're called	8	identification.)
9	risks.	9	MR. BALL: Hey, Adam, do you
10	MR. BALL: Objection.	10	guys have a translated version of this
11	Compound.	11	that I can look at?
12	A. I don't certain well,	12	MR. SLATER: I think so.
13	it's all how you define it. There's certain	13	Cheryll can confirm. If we don't
14	risk is confirmed, okay? It really, I guess,	14	we'll make one for you, but I think we
15	depends upon the context when you discuss	15	do.
16	risk.	16	MS. CALDERON: Give me one
17	I mean, I'm not an expert, you	17	second, I'll put it in the
18	know, you know, you know, like, you know, you	18	MR. SLATER: No problem. Take
19	know, to discuss that exactly definition, you	19	your time.
20	know, you know, of risk, but I know, you	20	(Pause.)
21	know, people use potential risks.	21	MR. SLATER: Are we good?
22	And also, you know, sometimes,	22	MR. BALL: I still don't have
1	you know, they just use, you know, like seems	23	it. Hold on, maybe I need to refresh,
24		24	sorry. No, I still I only have the
	Page 344		Page 346
1	BY MR. SLATER:	1	305. Do you have like a 305A or a
2	Q. The scientific consensus is	2	306?
3	that ingesting NDMA as a contaminant of	3	MS. CALDERON: I'm trying to
4	valsartan poses a health risk to those people	4	load it now. Just give me one second.
5	that take the pills, correct?	5	MR. BALL: Okay.
6	MR. BALL: Objection.	6	MR. SLATER: Just let me know.
7	Objection. Foundation, calls for	7	MS. CALDERON: All right. I
8	expert testimony, and speculative.	8	was on mute.
9	A. I think you already asked	9	Do you see it?
10	several times. You know, essentially this is	10	MR. BALL: Let me refresh. Is
11	the same question you asked before. I think	11	it 306?
12	I already answered that.	12	MS. CALDERON: I did 306-t.
13	BY MR. SLATER:	13	MR. BALL: Yep, got it. Thank
14	Q. Well, is the answer to that	14	you. I'm trying to open it now.
15	question yes? The answer is yes, right?	15	(Whereupon, Exhibit Number
16	MR. BALL: Objection.	16	ZHP-306t was marked for
17	Mischaracterizes his earlier	17	identification.)
18	testimony.	18	MR. BALL: Cheryll, that's not
19	A. As I said, you know, our	19	showing me any there we go, okay.
20	decision was based upon potential risk to	20	Sorry. It opened.
21	humans.	21	MS. CALDERON: Okay.
	MR. SLATER: Cheryll, we can	22	MR. BALL: It just look a long
122	,	ı ——	=
22	•	23	time to open, sorry.
22 23 24	take that one down. Give me one second to get organized, I will tell	23 24	time to open, sorry.

BY MR. SLATER: Q. Okay. On the screen we have 3 Exhibit – gosh, I don't know what number 4 we're up to. I lost track. 5 MS. CALDERON: 306. 6 MR. SLATER: 306. 7 Q. On the screen we have 8 Exhibit 306, which is an e-mail that was sent 10 e-mail to you? 11 A. It's Mr. Lin. 12 Q. Jinsheng Lin. Yes. 13 A. Yes, Jinsheng Lin. Yes. 14 Q. And just to refresh our 15 recollection again, as of 2018 what was his 16 position in your department? 17 A. I think he should be like 18 associate technical director. 19 Q. Mr. Lin wrote to you, and since 20 the e-mail its short, maybe you could tell us 21 what it says, please. 22 A. Sure. Yeah, basically, you 23 know, it's the list of the potential organic 24 impurity of valsartan basically. Yeah, 25 forence? 26 A. Q. On the screen we have 27 A. I don't know what number 28 the been controlled as a regular impurity, 29 d. If I understand what you've 30 leven saying is it's your testimony that 31 impurity, not as a nitrosamine impurity, is 32 that what you're telling me? 33 Leven say lease. 34 Yes, Jinsheng Lin. Yes. 35 A. Yes, Jinsheng Lin. Yes. 36 A. Yes, Jinsheng Lin. Yes. 37 A. Yes, Jinsheng Lin. Yes. 38 A. Yes, Jinsheng Lin. Yes. 39 A. Yes, Jinsheng Lin. Yes. 40 A. I shink he should be like 41 G. Li track. 41 G. Jinsheng Lin. Yes. 42 A. Sure. Yeah, basically, you 43 know, it's quite well-known. 44 Q. It lunderstand what you're telling me? 45 A. Yes, Jinsheng Lin. Yes. 46 A. Oh, yes, menhmm, it says, yes. 47 Correct? 48 A. Oh, yes, menhmm, it says, yes. 49 Q. And why did he point out that impurity K was not listed in this list of potential organic purities for valsartan? 48 Pagna 34 Sad, you know, for the adam of points out that impurity K was not listed in this list of potential organic impurities for valsartan? 40 Pagna 34 Sad, You know, from the very beguinning it has been canny in sty say sus as a listage on the very beguinning it has been canny in sty say sus as a last advour to you that impurity K was cont listed in this is of potential so what it says list of potential orga		PageID	: 82	131
2 Q. Okay. On the screen we have 4 we're up to. I lost track. 5 MS. CALDERON: 306. 6 MR. SLATER: 306. 7 Q. On the screen we have 8 Exhibit306, which is an e-mail that was sent to you on September 25, 2018. Who sent that 10 e-mail to you? 11 1 A. It's Mr. Lin. 12 Q. Jinsheng Lin. Yes. 14 Q. And just to refresh our recollection again, as of 2018 what was his position in your department? 15 recollection again, as of 2018 what was his position in your department? 16 e-mail to syou go whow, at his spoint, you know, at his was ontrolled as a regular impurity, is was not listed in this list of the potential organic purities for valsartan? 1 it's the list of the potential organic impurities, Adam, not purities. 1 MR. BALL: You said purities. 1 MR. SLATER: And hopefully verified in the will worry about this ion, was upload an English version for me? Thank you. THE WITNESS: Could you increase the scale? It's		· · · · · · · · · · · · · · · · · · ·		
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4 we're up to. I lost track. MS. CALDERON: 306. MR. SLATER: 306. Q. On the screen we have Exhibit306, which is an e-mail that was sent to you on September 25, 2018. Who sent that to e-mail to you? 1 A. It's Mr. Lin. 2 Q. Jinsheng Lin. Yes. 3 A. Yes, Jinsheng Lin. Yes. 4 Q. And just to refresh our 15 recollection again, as of 2018 what was his position in your department? A. I think he should be like 18 associate technical director. 19 Q. Mr. Lin wrote to you, and since 20 the e-mail is short, maybe you could tell us what it says, please. 22 A. Sure. Yeah, basically, you 23 know, it's quite well-known. 15 recollection again, as of 2018 what was his position in your department? 16 you have to refresh our 17 you know, from the very beginning it it sont of -you know, grot mit point, you know, it's quite well-known. 18 Q. If I understand what you've been saying is it's your testimony that impurity, is an e-mail that was sent impurity, is a group know, it's quite well-known. 19 Q. Mr. Lin wrote to you, and since 20 the e-mail is short, maybe you could tell us what it says, please. 21 A. Sure. Yeah, basically, you have it is ays that there's a list of the attachment. Yeah, essentially 22 it's the list of the potential organic impurity of valsartan basically. Yeah, at the was that it is. 23 A. Oh, yes, mm-hmm, it says, yes. 34 Q. It says that there's a list of potential organic purities for valsartan and points out that impurity K is not listed, recorder? 24 A. Oh, yes, mm-hmm, it says, yes. 25 Q. And why did he point out that impurity K was not listed in this list of potential organic purities for valsartan? 25 MR. BALL: You said purities. 26 MR. SLATER: Cheryll, download the - upload the English version first, let's get that to Rick first, and then well worry about this document. 26 MR. SLATER: No problem. 27 Can we go off? I just got a minute. 28 MR. BALL: You said purities. 29 Q. Oh. I'll ask it again. 30 Q. Mr. Jimsheng Lin. 31 A. Yes. 32 MR. BALL: Okay. That's fine. 33 Usalarian? 34 A. Sure. Yes. 35 MR. BALL:	2	Q. Okay. On the screen we have	2	you know. So because here it says list of
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24 A. I don't know. I don't know why 24 MR. SLATER: That's fine.				
	24	A. I don't know. I don't know why	24	MR. SLATER: That's fine.

	PageID	<u>: 82</u>	132
	Page 351		Page 353
1	That's probably a good idea.	1	MR. BALL: No, I'd like you to
2	MR. BALL: Okay. Go ahead.	2	provide a translation that's actually
3	MR. SLATER: Let's go off the	3	understandable. For example, I can
4	record, Judy.	4	read you some of what it says
5	MR. BALL: Yeah, go off the	5	MR. SLATER: No, I don't need
6	record.	6	you to. I'm saying let's go off
7	THE VIDEOGRAPHER: The time	7	the record for a second if we're going
8	right now is 8:14 a.m. We're off the	8	to discuss this.
	<u> </u>		
9	record.	9	MR. BALL: Okay.
10	(Whereupon, a recess was	10	THE VIDEOGRAPHER: The time
11	taken.)	11	right now is 8:30 a.m. We're off the
12	THE VIDEOGRAPHER: The time	12	record.
13	right now is 8:29 a.m. We're back on	13	(Off the record discussion.)
14	the record.	14	THE VIDEOGRAPHER: The time
15	BY MR. SLATER:	15	right now is 8:32 a.m. We're back on
16	Q. On the screen is a document	16	the record.
17	we've marked as Exhibit307. Do you see	17	BY MR. SLATER:
18	that?	18	Q. Looking at Box Number 5
19	A. Mm-hmm.	19	actually let's start at the top with the
20	Q. And what's the title of that	20	headings.
21	document? What does it say at the top?	21	The left-hand column the
22	A. It says "Drug Substance Product	22	heading is "Number," so we can understand
23	Deficiency Letter Progress," and then it	23	that. That's just a listing of each of the
24	looks like a date, 2020, March 19th.	24	deficiency letters?
<u> </u>			·
I	Page 352		
1	-	4	Page 354
1	Q. So this is a list of deficiency	1	A. Mm-hmm.
2	Q. So this is a list of deficiency letters having to do with the drug substances	2	A. Mm-hmm. Q. The next column next to Number,
2	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to?	2	A. Mm-hmm. Q. The next column next to Number, what does that heading say?
2 3 4	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes.	2 3 4	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name.
2 3 4 5	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the	2	 A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column
2 3 4 5 6	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could	2 3 4 5 6	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading?
2 3 4 5 6 7	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we	2 3 4 5	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market.
2 3 4 5 6 7 8	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got	2 3 4 5 6	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market,"
2 3 4 5 6 7 8 9	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually.	2 3 4 5 6 7	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market.
2 3 4 5 6 7 8 9	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got	2 3 4 5 6 7 8	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market,"
2 3 4 5 6 7 8 9	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually.	2 3 4 5 6 7 8 9	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold?
2 3 4 5 6 7 8 9	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one	2 3 4 5 6 7 8 9	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right.
2 3 4 5 6 7 8 9 10 11	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing?	2 3 4 5 6 7 8 9 10 11	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column
2 3 4 5 6 7 8 9 10 11 12	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What?	2 3 4 5 6 7 8 9 10 11 12	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading?
2 3 4 5 6 7 8 9 10 11 12 13	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What? MR. BALL: The English translation of this, it makes no sense	2 3 4 5 6 7 8 9 10 11 12 13	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading? A. The fourth column, you mean in
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What? MR. BALL: The English translation of this, it makes no sense at all, none. I'm sure Cheryll could	2 3 4 5 6 7 8 9 10 11 12 13 14	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading? A. The fourth column, you mean in terms of market, right? Q. The first column was number,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What? MR. BALL: The English translation of this, it makes no sense	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading? A. The fourth column, you mean in terms of market, right? Q. The first column was number, the second column was the product name, the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What? MR. BALL: The English translation of this, it makes no sense at all, none. I'm sure Cheryll could read it to you and let you know that it makes no sense.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading? A. The fourth column, you mean in terms of market, right? Q. The first column was number, the second column was the product name, the third was the market. What's the fourth
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What? MR. BALL: The English translation of this, it makes no sense at all, none. I'm sure Cheryll could read it to you and let you know that it makes no sense. We'll go ahead with the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading? A. The fourth column, you mean in terms of market, right? Q. The first column was number, the second column was the product name, the third was the market. What's the fourth column heading?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What? MR. BALL: The English translation of this, it makes no sense at all, none. I'm sure Cheryll could read it to you and let you know that it makes no sense. We'll go ahead with the deposition, and if I have questions	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading? A. The fourth column, you mean in terms of market, right? Q. The first column was number, the second column was the product name, the third was the market. What's the fourth column heading? A. Oh, I'm sorry. Basically it's
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What? MR. BALL: The English translation of this, it makes no sense at all, none. I'm sure Cheryll could read it to you and let you know that it makes no sense. We'll go ahead with the deposition, and if I have questions regarding what Dr. Li is reading, we	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading? A. The fourth column, you mean in terms of market, right? Q. The first column was number, the second column was the product name, the third was the market. What's the fourth column heading? A. Oh, I'm sorry. Basically it's the summary of the main issue. Yeah.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What? MR. BALL: The English translation of this, it makes no sense at all, none. I'm sure Cheryll could read it to you and let you know that it makes no sense. We'll go ahead with the deposition, and if I have questions regarding what Dr. Li is reading, we can we can address that, but	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading? A. The fourth column, you mean in terms of market, right? Q. The first column was number, the second column was the product name, the third was the market. What's the fourth column heading? A. Oh, I'm sorry. Basically it's the summary of the main issue. Yeah. Q. What is the fifth column
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What? MR. BALL: The English translation of this, it makes no sense at all, none. I'm sure Cheryll could read it to you and let you know that it makes no sense. We'll go ahead with the deposition, and if I have questions regarding what Dr. Li is reading, we can we can address that, but MR. SLATER: Do you want to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading? A. The fourth column, you mean in terms of market, right? Q. The first column was number, the second column was the product name, the third was the market. What's the fourth column heading? A. Oh, I'm sorry. Basically it's the summary of the main issue. Yeah. Q. What is the fifth column heading?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. So this is a list of deficiency letters having to do with the drug substances and their progress in being responded to? A. Yes. Q. Looking at the MR. SLATER: If you could scroll up a little bit, Cheryll, so we get all of Box 5. Great. You've got to scroll down a little bit, actually. MR. BALL: Adam, can I say one thing? MR. SLATER: What? MR. BALL: The English translation of this, it makes no sense at all, none. I'm sure Cheryll could read it to you and let you know that it makes no sense. We'll go ahead with the deposition, and if I have questions regarding what Dr. Li is reading, we can we can address that, but	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Mm-hmm. Q. The next column next to Number, what does that heading say? A. That's the product name. Q. What's the third column heading? A. It's the market. Q. When you say "the market," meaning the country where it's sold? A. Right. Q. What's the fourth column heading? A. The fourth column, you mean in terms of market, right? Q. The first column was number, the second column was the product name, the third was the market. What's the fourth column heading? A. Oh, I'm sorry. Basically it's the summary of the main issue. Yeah. Q. What is the fifth column

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1	summary of the main deficiency or the main	1	refused to share with us. So you may
2	issue?	2	proceed if you want, but
3	Q. No. What I'm asking you is,	3	MR. SLATER: What I said is I
4	we've been going across the top row where the	4	don't have a translation of the entire
5	headings where the titles of each of the	5	document. That's why I asked Dr. Li
	columns is set forth.	6	to translate.
6			
7	So the left-hand column, the	7	But why don't we go off the
8	first column was number.	8	record. Hang on. Let's go off the
9	A. Uh-huh.	9	record.
10	Q. The second column was product	10	THE VIDEOGRAPHER: The time
11	name.	11	right now is 8:36 a.m. We're off the
12	A. Right.	12	record.
13	Q. The third column was the	13	(Off the record discussion.)
14	market.	14	THE VIDEOGRAPHER: The time
15	A. Right.	15	right now is 8:36 a.m. We're back on
16	Q. The fourth column was the	16	the record.
17	summary of the main issue.	17	BY MR. SLATER:
18	•	18	_
1	I'm asking you what the heading		Q. Looking at line number 2 in the
19	on the fifth column is now.	19	fourth column, can you tell me what that
20	A. Oh, I'm sorry. Okay. That's	20	says, please?
21	the progress. Yeah, current status and the	21	A. You mean the number 1 in the
22	progress.	22	first column, right?
23	Q. Okay. And what's the last	23	Q. Well, we just went through
24	column, the sixth column?	24	number 1, right?
	Page 356		Page 358
1	A. That's the expected submission,	1	A. Okay. Yeah, okay, yeah.
2	•		7. Chay. Fourt, Chay, your.
	VOLL know to the regulatory agencies	2	Let me ask the guestion
	you know, to the regulatory agencies.	2	Q. Let me ask the question.
3	Q. When you say "the expected	3	In the fourth column, which is
3 4	Q. When you say "the expected submission," is that a date or	3 4	In the fourth column, which is the heading you said was summary of the main
3	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month,	3 4 5	In the fourth column, which is the heading you said was summary of the main issue
3 4 5 6	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah.	3 4 5 6	In the fourth column, which is the heading you said was summary of the main issue A. Right.
3 4 5	 Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, 	3 4 5 6 7	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say?
3 4 5 6	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row,	3 4 5 6	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and
3 4 5 6 7	 Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, 	3 4 5 6 7	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say?
3 4 5 6 7 8	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row,	3 4 5 6 7 8	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and
3 4 5 6 7 8 9	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5.	3 4 5 6 7 8 9	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled
3 4 5 6 7 8 9 10	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep.	3 4 5 6 7 8 9 10	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the
3 4 5 6 7 8 9 10 11 12	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for	3 4 5 6 7 8 9 10 11 12	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United
3 4 5 6 7 8 9 10 11 12 13	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5?	3 4 5 6 7 8 9 10 11 12 13	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct?
3 4 5 6 7 8 9 10 11 12 13	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5? A. Valsartan.	3 4 5 6 7 8 9 10 11 12 13 14	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct? MR. BALL: Objection. Calls
3 4 5 6 7 8 9 10 11 12 13 14 15	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5? A. Valsartan. Q. What is the market?	3 4 5 6 7 8 9 10 11 12 13 14 15	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct? MR. BALL: Objection. Calls for expert calls for a legal
3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5? A. Valsartan. Q. What is the market? A. US market.	3 4 5 6 7 8 9 10 11 12 13 14 15 16	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct? MR. BALL: Objection. Calls for expert calls for a legal conclusion.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5? A. Valsartan. Q. What is the market? A. US market. Q. Then in the summary of the main	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct? MR. BALL: Objection. Calls for expert calls for a legal conclusion. A. Let me provide a more complete
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5? A. Valsartan. Q. What is the market? A. US market. Q. Then in the summary of the main issue, tell me if I understand this	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct? MR. BALL: Objection. Calls for expert calls for a legal conclusion. A. Let me provide a more complete background, okay?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5? A. Valsartan. Q. What is the market? A. US market. Q. Then in the summary of the main issue, tell me if I understand this correctly. The first line has to do with	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct? MR. BALL: Objection. Calls for expert calls for a legal conclusion. A. Let me provide a more complete background, okay? So, as I mentioned, you know,
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5? A. Valsartan. Q. What is the market? A. US market. Q. Then in the summary of the main issue, tell me if I understand this correctly. The first line has to do with reprocessing plan for the NDMA and the NDEA	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct? MR. BALL: Objection. Calls for expert calls for a legal conclusion. A. Let me provide a more complete background, okay? So, as I mentioned, you know, since the very beginning, you know,
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5? A. Valsartan. Q. What is the market? A. US market. Q. Then in the summary of the main issue, tell me if I understand this correctly. The first line has to do with reprocessing plan for the NDMA and the NDEA for the old process?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct? MR. BALL: Objection. Calls for expert calls for a legal conclusion. A. Let me provide a more complete background, okay? So, as I mentioned, you know, since the very beginning, you know, impurity K and you know, has been
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5? A. Valsartan. Q. What is the market? A. US market. Q. Then in the summary of the main issue, tell me if I understand this correctly. The first line has to do with reprocessing plan for the NDMA and the NDEA for the old process? MR. BALL: Adam, I'm going to	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct? MR. BALL: Objection. Calls for expert calls for a legal conclusion. A. Let me provide a more complete background, okay? So, as I mentioned, you know, since the very beginning, you know, impurity K and you know, has been controlled as a regular impurity, okay, at
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. When you say "the expected submission," is that a date or A. Or day or, yeah, or month, whatever, yeah. Q. Now, applying those headings, we'll be able to walk through the fifth row, number 5. Do you see number 5 down there? A. Mm-hmm, yep. Q. What is the product name for row 5? A. Valsartan. Q. What is the market? A. US market. Q. Then in the summary of the main issue, tell me if I understand this correctly. The first line has to do with reprocessing plan for the NDMA and the NDEA for the old process?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	In the fourth column, which is the heading you said was summary of the main issue A. Right. Q what does number 2 say? A. It says, impurity K and impurity L, it said required to be controlled as nitrosamine impurity. Q. And that would have been the requirement from the FDA in the United States, correct? MR. BALL: Objection. Calls for expert calls for a legal conclusion. A. Let me provide a more complete background, okay? So, as I mentioned, you know, since the very beginning, you know, impurity K and you know, has been

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1 closed structure analog of impurity K. So essentially it's like the impurity of the 3 impurity, okay.

And based upon the quantitative, you know, structure-activity relationship, okay, impurity L, you know, can be also treated as a regular impurity, okay.

8 And so with regard to this 9 particular request or the deficiency letter 10 from the FDA, right, during -- well, this is because we filed an amendment, okay, as far 11 12 as I understand, okay, to the FDA submitting 13 our, you know, optimized or -- you know, with a separate quenching valsartan, you know, 15 improved process, okay?

So in that submission we 17 were -- you know, we were referring to, you 18 know, the control of, you know, impurity K as 19 a regular impurity by pointing or referencing 20 European, you know, you know, you know, 21 regulatory documents, okay.

And then FDA responded, right? 23 I think that was like about, you know, more 24 than one year ago, okay. FDA basically says.

you know, CEMAT to develop a -- like a

- quantitative method to give a more accurate,
- you know, you know, method to control, you
- know, you know, to see either, you know, you
- know, impurity K or L can be controlled as a
- nitrosamine impurity, which means, you know,
- a specification of like 26.5 nanogram per
- day, okay? 8
- 9 So I think, yeah, this is, you
- 10 know, you know, you know, is -- basically,
- 11 again, if my memory, you know, you know, you
- 12 know, is correct, so this is basically how,
- you know, this came out, right? 13

14 I think in the end, based upon 15 our study, impurity K could not be, you know,

controlled at such a low level, okay, due to

17 the nature of the process chemistry. Okay?

18 So then after that, we revert

19 to another, you know, like option 1, right,

20 because FDA say, you know, you need to do the

- 21 in vivo animal study. And if the animal
- 22 study results is negative, then, you know,
- 23 you communicate that to us and then we'll --
- you know, basically, you know, they will 24

Page 360

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1 okay, if I, you know, remember, you know,

2 correctly, I think it basically says for

3 impurity K, although it said your statement

4 saying, you know, impurity K is Ames

5 negative, right?

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6 And however, okay, at that point, okay, FDA says we still need you guys 8 to, you know -- you have some like -- you know, like two or three options, okay, to go 10 ahead.

First, we require you to do, 12 you know, in vivo animal studies, right, so 13 that's number one.

Number two, if you, you know, 15 was not able to do the animal study, then you 16 need to control as, you know, as a 17 nitrosamine or treated as a nitrosamine 18 impurity. Okay. So that's where, you know -- you know, how the issue basically, 19 vou know, came out.

20 21 So for this specific request, 22 right, and from our regulatory, you know, you 23 know, affairs department, I think, you know, 24 they probably, you know, requires, you know, Page 362

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decide whether, you know, it can be qualified as a regular impurity. 2

3 So in the end we, you know, contracted an external, you know, CRO, okay, to do a particular in vivo animal study; it's 5 called a comet assay.

This particular comet assay is 8 also mentioned in the M7, okay, as part of 9 the in vivo, you know, test, you know, 10 evaluating the, you know, the -- ultimately

the, you know, the potential, you know, 11

12 carcinogenic, you know, potential. Okay.

13 So -- yeah. So afterwards, you 14 know, because from the process, as I said,

15 based upon the nature of the process, you

16 know, you just cannot control at such a low

17 level. So we -- as I said, we revert to

18 option one, okay.

19 So we have to prepare enough quantity and then, you know, send out for 20 21 this comet assay. And the results of the 22 comet assay cannot be negative. Okay.

And then I think in the beginning of this year we submitted, you

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Page 363

know, this result to the FDA, okay? So this 2 exactly, you know, how everything evolved or 3 happened.

4 BY MR. SLATER:

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5 Coming back to my question, was Q. 6 it the FDA that directed ZHP to control impurities K and L as nitrosamine impurities?

I think I already explained it quite clearly. They gave us two options.

9 One option is to do in vivo 10 11 animal studies. Okay. So basically what 12 that means is if in vivo animal study cannot 13 be negative, you know, they may, you know, 14 accept our, you know, you know, argument 15 that, you know, impurity K can be treated as 16 a regular impurity, which is already or still 17 being done, you know, based upon the policy 18 from European regulatory agencies. Okay.

19 So the option two is if we, you 20 know, is not able, like it was not able to do 21 that, for whatever the reason, right, lack of 22 resources or no CRO, for example, you know,

23 you know, in China would do that kind of

24 study, then we need to control impurity K and

L as, you know, nitrosamine, like a default,

2 you know, specification, which, as I

3 mentioned, 26.5 nanogram per day.

You said that number 2 Q. 5 indicated that impurity K and impurity L were required to be controlled in accordance with nitrosamine impurities. I'm simply asking was it the FDA that was requiring that.

> MR. BALL: Objection. Asked and answered, and it mischaracterizes his earlier testimony.

12 Again, you know, this statement 13 is taking, you know, you know, out of the context. Okay. In this particular case, probably in every cases, okay, you cannot 15 16 taking, you know, your question out of the 17 context. Okay. So I already repeated it 18 twice, right?

19 So there's two options, okay. 20 Only if we are not able to do the option one. 21 then, you know, we will need to do the option 22 two, which is to control that as nitrosamine 23 default values. Okay. So, you know, so

24 otherwise, you know, you are basically, you

Page 365

know, not saying, you know, you know, you

know -- I mean, it would be very much

misleading, okay?

4 BY MR. SLATER:

Q. The deficiency letter that's

being addressed in row 5 was a deficiency 6

letter from the FDA, correct?

8 Α. It is for FDA, based upon our, 9 you know, the amendment to submit our, you

know, newly improved, you know, valsartan

11 process.

And by the way, you know, by 13 the way, this process has already been accepted by the European regulatory agencies. 14 We already resume the supply of valsartan 15 drug substances to the European market as 16 well as to the Chinese market.

> MR. SLATER: Let's take that document down, and the next document we'll go to which will be Exhibit 308, it will be PRINSTON00285416.

22 (Whereupon, Exhibit Number 23 ZHP-308 was marked for 24

identification.)

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BY MR. SLATER:

2 On the screen we have Q.

3 Exhibit 307, which looks like it was -- has a

fax date at the top of March 18, 2020. 5 MS. CALDERON: Adam, it's 308.

6 I'm sorry to interrupt.

7 MR. SLATER: The exhibit number 8 is 308?

9 BY MR. SLATER:

10 Exhibit 308, which has a March 11 2020 fax stamp at the top, is a letter from

the FDA to Huahai US as US agent for ZHP. 12 13 Do you see that?

Yes, I see that. Α.

14

And it --15 Q.

MR. SLATER: Scroll down,

17 please, Cheryll.

This indicates, "Dear Sir: 18

This communication is in reference to your 19

20 Type II Drug Master File for Valsartan USP

21 (Process II)."

22 And I want to stop there. What

23 is Valsartan Process II?

Process II, I think it is -- by

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	Page 367		Page 369
1	this time it should have been the zinc	1	treat NDMA or NDEA as I need to rephrase
2	chloride process.	2	the question.
3	MR. SLATER: Let's go to the	3	At no time did the FDA permit
4	second page, please, paragraph	4	ZHP to treat NDMA as anything other than a
5	number 5.	5	nitrosamine impurity once the FDA became
			· · · · · · · · · · · · · · · · · · ·
6	Q. This states, "In the	6	aware of it, correct?
7	January 21, 2020 amendment you stated in	7	A. We're talking about here, you
8	3.2.S.2.2 that impurities K and L were	8	know, impurity K and L. I mean, now you're
9	negative in the Ames assay and that these	9	switch, you're talking about NDMA.
10	could be controlled as 'any single impurity'	10	Q. Okay. I asked do you want
11	at NMT 0.10 percent in the drug substance.	11	me to reask my question?
12	Please note that our clinical group has	12	A. Sure.
13	stated that Ames assays may not fully	13	Q. At any time did the FDA tell
14	characterize the mutagenicity of N-nitroso	14	ZHP that it did not have to control NDMA as a
15	compounds due to species-specific differences	15	nitrosamine impurity?
16	in metabolic activation of potential	16	A. No.
17	•	17	Q. At any time did the FDA tell
	mutagens."		
18	Do you see what I just read?	18	ZHP that it did not have to control NDEA as a
19	A. Yeah, mm-hmm.	19	nitrosamine impurity?
20	Q. The letter continues, "These	20	A. No.
21	N-nitroso compounds are identified as part of	21	Q. The impurity that led to the
22	the 'cohort of concern' for potent	22	recall of the zinc chloride process valsartan
23	carcinogenic effects, therefore additional	23	was NDMA, correct?
24	caution and a more robust characterization of	24	A. Yes.
	Page 368		Page 370
1	their mutagenic potential is warranted. We	1	Q. The impurities that led to
2	recommend the following regarding the nitrosc		·
3	valsartan and nitroso valsartan methyl ester	3	MR. SLATER: Okay. I think we
J	valsarian and milioso valsarian metriyi ester		
1	impurition in valentan drug substance " and		•
4	impurities in valsartan drug substance," and	4	finished that document. We'll take
5	then there's two	4 5	finished that document. We'll take that down.
5 6	then there's two A. Two options.	4 5 6	finished that document. We'll take that down. Cheryll, let's now go to
5 6 7	then there's two A. Two options. Q two options indicated.	4 5 6 7	finished that document. We'll take that down. Cheryll, let's now go to ZHP00387118, please.
5 6 7 8	then there's two A. Two options. Q two options indicated. Do you see that?	4 5 6	finished that document. We'll take that down. Cheryll, let's now go to ZHP00387118, please. (Whereupon, Exhibit Number
5 6 7 8 9	then there's two A. Two options. Q two options indicated. Do you see that? A. Oh yeah. Yeah. That's exactly	4 5 6 7	finished that document. We'll take that down. Cheryll, let's now go to ZHP00387118, please.
5 6 7 8	then there's two A. Two options. Q two options indicated. Do you see that?	4 5 6 7 8	finished that document. We'll take that down. Cheryll, let's now go to ZHP00387118, please. (Whereupon, Exhibit Number
5 6 7 8 9	then there's two A. Two options. Q two options indicated. Do you see that? A. Oh yeah. Yeah. That's exactly	4 5 6 7 8 9	finished that document. We'll take that down. Cheryll, let's now go to ZHP00387118, please. (Whereupon, Exhibit Number ZHP-309 was marked for
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5 6 7 8 9 10 11 12	then there's two A. Two options. Q two options indicated. Do you see that? A. Oh yeah. Yeah. That's exactly what I said, two options. Q. Number one says, "Reduce Impurities K and L in your drug substance to	4 5 6 7 8 9 10 11 12	finished that document. We'll take that down. Cheryll, let's now go to ZHP00387118, please. (Whereupon, Exhibit Number ZHP-309 was marked for identification.) BY MR. SLATER: Q. On the screen we have what
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5 6 7 8 9 10 11 12 13 14	then there's two A. Two options. Q two options indicated. Do you see that? A. Oh yeah. Yeah. That's exactly what I said, two options. Q. Number one says, "Reduce Impurities K and L in your drug substance to levels that are below the reporting threshold of 0.03 parts per million."	4 5 6 7 8 9 10 11 12 13 14	finished that document. We'll take that down. Cheryll, let's now go to ZHP00387118, please. (Whereupon, Exhibit Number ZHP-309 was marked for identification.) BY MR. SLATER: Q. On the screen we have what we've now marked as Exhibit gosh, I should know what I'm talking about before I start
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	then there's two A. Two options. Q two options indicated. Do you see that? A. Oh yeah. Yeah. That's exactly what I said, two options. Q. Number one says, "Reduce Impurities K and L in your drug substance to levels that are below the reporting threshold of 0.03 parts per million." Do you see that? A. Mm-hmm. Q. And the second option is to "characterize each impurity in an in vivo gene mutation assay," and then it describes that. Do you see that?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	finished that document. We'll take that down. Cheryll, let's now go to ZHP00387118, please. (Whereupon, Exhibit Number ZHP-309 was marked for identification.) BY MR. SLATER: Q. On the screen we have what we've now marked as Exhibit gosh, I should know what I'm talking about before I start talking about the exhibit. On the exhibit rephrase. On the screen is Exhibit 309, which is a scientific literature article. Do you see that? A. Yeah, mm-hmm. Q. And it's titled, excuse my

	<u>PageiD</u>	<u>. 82</u>	157
	Page 371		Page 373
1	Adducts of Formaldehyde and Their Application	1	Dutton, Heath, and Druckrey nearly 50 years
2	to Rats Treated with NDMA or	2	ago, well-established pathways of metabolic
3	4-(Methylnitrosamino)-1-(3-pyridyl)-1-	3	activation of nitrosamines involving
4	butanone," and it says that it was a 2007	4	cytochrome P450-mediated a-methyl
5	publication.	5	hydroxylation have been described in the
6	Do you see that?	6	literature."
7	A. Yes.	7	Do you see what I'm reading?
8	Q. And this article, I believe	8	A. Mm-hmm.
9	well, rephrase.	9	Q. It says further, "As shown in
10	This is an article that you've	10	Scheme 1, methyl hydroxylation of NDMA and
11	read, correct?	11	NNK yields intermediates 5 and 9, which
12	A. I have not gone through this	12	spontaneously release reactive
13	particular article.	13	diazohydroxides 6 and 10. These
14	Q. Are you sure about that?	14	diazohydroxides or the corresponding
15	A. Yeah, I'm pretty sure. I may	15	diazonium ions react with DNA, producing
16	have I don't know, I may have downloaded	16	adducts such as 06-methyl-dGuo from NDMA and
17	it, but I can tell you I just haven't gone	17	06-pyridyloxobutyl-dGuo (06-POB-dGuo) from
18	through, you know, this particular article in	18	NNK."
19	details.	19	I want to stop there. This is
20			talking about these nitrosamines reacting
	9 9	20	-
21	didn't complete introducing the article so	21	with and causing changes to DNA, correct?
22	let me just make sure for the record I	22	A. Could we just scroll up a
23	address it rephrase.	23	little bit? I just want to take a look at
24	This article was written by	24	the, you know, the reaction scheme.
	Page 372		Page 374
1	it looks like there's a handful of authors,	1	Q. Yes.
2	it looks like there's a handful of authors, just for the record their names are Mingyao	2	Q. Yes.A. Okay. So what is the question?
2	it looks like there's a handful of authors, just for the record their names are Mingyao Wang, Guang Cheng, Peter Villalta, and		Q. Yes. A. Okay. So what is the question? I'm sorry.
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	Page 375		Page 377
1	NDMA, NNK, and other N-nitroso compounds have	1	want to study the cancer in those laboratory
2	been extensively studied," and I want to stop	2	animals, correct?
3	there.	3	MR. BALL: Objection. Calls
4	And you would agree with me	4	for expert testimony, testimony
5	that there are a lot of studies talking about	5	foundation, vague.
6	the fact that NDMA and NNK and other	6	 A. Based upon the description in
7	nitrosamine are carcinogenic, correct?	7	this particular paragraph, or in particular
8	MR. BALL: Objection. Vague.	8	the last sentences, it didn't say that, you
9	A. Based upon the statement here,	9	know. It just said the first evidence
10	it looks like, yeah, that's the case. But	10	formaldehyde NDMA I'm sorry
11	again, you know, based upon, you know, my	11	formaldehyde DNA adducts are formed in the
12	knowledge, you know, as I said, of these	12	livers of rats treated with NDMA and NNK. So
13	studies, you know, they were based upon	13	it didn't say anything else.
14	animal studies.	14	MR. SLATER: Let's go now to
15	BY MR. SLATER:	15	the page where the Bates number is
16	Q. The last sentence of this	16	123, the last three digits, please.
17	section says, "In this paper, we present the	17	It's the "Discussion" left-hand column
18	first evidence that formaldehyde DNA adducts	18	on that page. I just want to bring up
19	are formed in the lung and liver of rats	19	the discussion there. Perfect. Thank
20	treated with NDMA and NNK."	20	you.
21	Do you see that?	21	BY MR. SLATER:
22	A. Yes.	22	Q. Here now in the "Discussion"
23	Q. So when they rephrase.	23	part of this article, which was provided to
24	When they discuss treating rats	24	us by ZHP from ZHP's own files, it states
	Page 376		Page 378
1	with NDMA, they're talking about giving NDMA	1	that first "The results of this study provide
2	to these rats in order to intentionally cause	2	the first evidence for the presence of
3	them to develop cancer, correct?	3	formaldehyde DNA adducts in laboratory
4	MR. BALL: Objection. Vague,	4	animals."
5	and mischaracterizes the document.	5	Do you see that?
6	A. Looks like this is what it	6	A. Uh-huh, sure.
7	says.	7	Q. If we go down a little further
8	BY MR. SLATER:	8	in that paragraph, about halfway down it
9	Q. And you know that NDMA has been	9	says, "The method was applied to rats treated
10	used for many years, and it's well understood	10	with the carcinogenic nitrosamines NDMA and
11	to give cancer to laboratory animals so they	11	NNK, and the results demonstrate for the
12	can then be studied, because it's so	12	first time that formaldehyde DNA adducts are
13	efficient at causing cancer, correct?	13	produced from these carcinogens, in addition
14	MR. BALL: Objection. Calls	14	to the well-characterized adducts, which
15	for expert testimony, foundation,	15	result from diazohydroxides formed in
16	vague.	16	nitrosamine metabolism."
17	A. As I indicated, or as I	17	Do you see that?
18	answered before, animal study, you know, at a	l	A. Yes. Let me read it through
19	very high dose, you know, it issues	19	again.
20	carcinogenic to the animals.	20	(Witness reviewing document.)
21	BY MR. SLATER:	21	A. Okay, yeah.
22	Q. It's accepted in the scientific	22	Q. When this refers to NDMA as a
I	a. It a accepted in the colonities	ı – –	S. The the lead to Hellin as a

23 community that NDMA very efficiently causes 23 carcinogenic nitrosamine, that means from a

24

scientific perspective that it's a

24 cancer in laboratory animals when scientists

Page 379	
1 490 010	Page 381
1 nitrosamine that causes cancer, correct? 1 Q. Do you see Exhibit 31	310 in front
2 MR. BALL: Objection. Vague, 2 of you?	
3 calls for expert testimony, 3 A. Yes, I do.	
4 mischaracterizes the document. 4 Q. And you've mentioned	d tha ICU
, , , , , , , , , , , , , , , , , , , ,	
5 A. I mean, again, as I, you know, 5 guidelines during the course of t	
6 answered previously, it's carcinogenic to 6 deposition, and this is the one	
7 animal you know, laboratory animals, and 7 MR. SLATER: If you co	could
8 it's, you know, it's a probable carcinogenic 8 scroll up a little, Cheryll.	
9 to humans. 9 Q. It will show that it was	dated
10 BY MR. SLATER: 10 February 6, 2013.	
11 Q. You said "it's a probable 11 Do you see that?	
12 carcinogenic to humans"? That's the last 12 A. Mm-hmm.	
13 part you said? 13 Q. The title of this docume	nent is
14 A. Yes. 14 "Assessment and Control of DN	NA Reactive
15 MR. SLATER: Okay. We can take 15 (Mutagenic) Impurities in Pharm	
this document down now. Just give me 16 Limit Potential Carcinogenic Ris	
17 a second. I'll find the next one 17 says then "M7."	SK. Allult
1 ' '	
Cheryll, let's go now to the 19 A. Mm-hmm.	
20 2013 ICH Consensus Guideline, please. 20 Q. Just to be clear on the	
21 Thank you. 21 and the purpose of this document	
22 (Whereupon, Exhibit Number 22 prevent human beings from deve	veloping cancers
23 ZHP-310 was marked for 23 as a result of pharmaceutical dru	rugs, correct?
24 identification.) 24 MR. BALL: Objection.	
Page 380	Page 382
1 MR. SLATER: Sorry, I'm having 1 Foundation.	. ago 002
2 trouble with my binder clip here. I 2 A. It's already, you know	ow stated
3 feel like I have to get my binder 3 very clear, right? It's for the p	
4 clips in place before I can move to 4 limit the potential carcinogenia	nurnaga ta
1 4 CIDS III DIACE DEIDIE I CAIT HOVE LO 1 4 IIIIIIL LIE DOLEHBAL CAICHOGEH	
5 the next thing. 5 BY MR. SLATER:	nic risk.
5 the next thing. 5 BY MR. SLATER: 6 MR. BALL: I have the same 6 Q. It's to limit the poten	nic risk. ntial
5 the next thing. 5 BY MR. SLATER: 6 MR. BALL: I have the same 7 problem from time to time. I hate 7 carcinogenic risk for human b	ntial beings ingesting
5 the next thing. 6 MR. BALL: I have the same 7 problem from time to time. I hate 8 when they flip off of everything and 5 BY MR. SLATER: 6 Q. It's to limit the poten 7 carcinogenic risk for human be 8 pharmaceutical products, core	ntial beings ingesting
5 the next thing. 6 MR. BALL: I have the same 7 problem from time to time. I hate 8 when they flip off of everything and 9 go all over my office. 5 BY MR. SLATER: 6 Q. It's to limit the poten 7 carcinogenic risk for human b 8 pharmaceutical products, core 9 A. Yes.	ntial beings ingesting orrect?
5 the next thing. 6 MR. BALL: I have the same 7 problem from time to time. I hate 8 when they flip off of everything and 5 BY MR. SLATER: 6 Q. It's to limit the poten 7 carcinogenic risk for human be 8 pharmaceutical products, core	ntial beings ingesting orrect?
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5 the next thing. 6 MR. BALL: I have the same 7 problem from time to time. I hate 8 when they flip off of everything and 9 go all over my office. 10 MR. SLATER: Yep, they squeeze 11 off and they fly all over. 5 BY MR. SLATER: 6 Q. It's to limit the poten 7 carcinogenic risk for human b 8 pharmaceutical products, core 9 A. Yes. 10 Q. More specifically, it's 11 to limit that potential carcinog	ntial beings ingesting rrect? t's seeking genic risk as nutagenic
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5 the next thing. 6 MR. BALL: I have the same 7 problem from time to time. I hate 8 when they flip off of everything and 9 go all over my office. 10 MR. SLATER: Yep, they squeeze 11 off and they fly all over. 12 MR. BALL: Yep, exactly. 13 BY MR. SLATER: 14 Q. Looking now at this exhibit, 15 which is 16 MR. SLATER: Is this 310? 17 Gosh, am I ever right about the 18 WMR. SLATER: 19 Q. It's to limit the poten 7 carcinogenic risk for human b 8 pharmaceutical products, corn 9 A. Yes. 10 Q. More specifically, it's 11 to limit that potential carcinog 12 a result of DNA reactive or median impurities in those pharmaceutical products, corn 9 A. Yes. 11 to limit that potential carcinog 12 a result of DNA reactive or median impurities in those pharmaceutical products, corn 9 A. Yes. 11 to limit that potential carcinog 12 a result of DNA reactive or median impurities in those pharmaceutical products, corn 13 by Mr. SLATER: 13 impurities in those pharmaceutical products, corn 14 correct; 15 MR. BALL: Objection 16 Foundation. 17 A. Based upon this title	ntial beings ingesting brect? t's seeking genic risk as nutagenic eutical products, on. e, yes.
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	PageID PageID	<u>: 82</u>	140
	Page 383		Page 385
1	"General Principles," the first sentence	1	pronounce that?
2	says, "The focus of this guideline is on DNA	2	 Usually pronounce it degradant.
3	reactive substances that have a potential to	3	Q. Okay. I'll go with your
4	directly cause DNA damage when present at low	4	pronunciation.
5	levels leading to mutations and therefore,	5	Section 5.2 is titled
6	potentially causing cancer."	6	"Degradants." And if we go down to the
7	So that's giving some overview	7	second to last paragraph in that section it
8	of what the purpose of this standard is,	8	says, "Knowledge of relevant degradation
9	correct?	9	pathways can be used to help guide decisions
10	A. Mm-hmm.	10	on the selection of potential degradation
11	Q. Going to the second paragraph,	11	products to be evaluated for mutagenicity,
12	it starts out, "A Threshold of Toxicological	12	e.g., from degradation chemistry principles,
13	Concern (TTC) concept was developed to define	13	relevant stress testing studies, and
14	an acceptable intake for any unstudied	14	development stability studies."
15	chemical that will not pose a risk of	15	I want to stop there and first
16	carcinogenicity or other toxic effects."	16	ask you what is what is a degradation
17	Do you see that?	17	pathway? What does that mean?
18	A. Mm-hmm.	18	A. Well, basically how a drug
19	Q. So the threshold of	19	you know, a drug substance will decompose,
		20	
20	toxicological concern is, according to this		you know, to form, you know, maybe sometimes,
21	document, applicable to a certain class of	21	you know, first through an intermediate and
22	pharmaceutical products, correct?	22	then to its final product. So basically it's
23	A. Looks like.	23	just a pathway, you know, or sometimes you
24	MR. SLATER: Cheryll, could you	24	may call it a mechanism, a degradation
	Page 384		Page 386
1	coroll down a little bit on we can get		
	scroll down a little bit so we can get	1	mechanism.
2	that perfect. Thank you.	2	Q. A degradation pathway can also
3	that perfect. Thank you. Q. At the end of that paragraph it		Q. A degradation pathway can also include decomposition of an ingredient in a
3 4	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified	2 3 4	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase.
3	that perfect. Thank you. Q. At the end of that paragraph it	2 3	Q. A degradation pathway can also include decomposition of an ingredient in a
3 4	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be	2 3 4	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase.
3 4 5	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even	2 3 4 5	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can
3 4 5 6	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be	2 3 4 5 6	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase.
3 4 5 6 7	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant	2 3 4 5 6 7	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to
3 4 5 6 7 8	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant carcinogenic risk. This group of high	2 3 4 5 6 7 8	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to decomposition yielding impurity, correct?
3 4 5 6 7 8 9	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant carcinogenic risk. This group of high potency mutagenic carcinogens ('cohort of	2 3 4 5 6 7 8 9	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to decomposition yielding impurity, correct? A. To be precise
3 4 5 6 7 8 9 10	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant carcinogenic risk. This group of high potency mutagenic carcinogens ('cohort of concern') comprises aflatoxin-like,	2 3 4 5 6 7 8 9	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to decomposition yielding impurity, correct? A. To be precise MR. BALL: Objection. Asked
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3 4 5 6 7 8 9 10 11 12 13 14	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant carcinogenic risk. This group of high potency mutagenic carcinogens ('cohort of concern') comprises aflatoxin-like, N-nitroso-, and azoxy-compounds." Correct? A. Yes. Q. And the N-nitroso compounds include NDMA, correct?	2 3 4 5 6 7 8 9 10 11 12 13	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to decomposition yielding impurity, correct? A. To be precise MR. BALL: Objection. Asked and answered. A. Sorry, yeah. To be precise, the degradants that we discuss here or the document discuss
3 4 5 6 7 8 9 10 11 12 13 14 15	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant carcinogenic risk. This group of high potency mutagenic carcinogens ('cohort of concern') comprises aflatoxin-like, N-nitroso-, and azoxy-compounds." Correct? A. Yes. Q. And the N-nitroso compounds include NDMA, correct? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to decomposition yielding impurity, correct? A. To be precise MR. BALL: Objection. Asked and answered. A. Sorry, yeah. To be precise, the degradants that we discuss here or the document discuss here is typically related to after the making
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant carcinogenic risk. This group of high potency mutagenic carcinogens ('cohort of concern') comprises aflatoxin-like, N-nitroso-, and azoxy-compounds." Correct? A. Yes. Q. And the N-nitroso compounds include NDMA, correct? A. Yes. Q. And N-nitroso compounds include NDEA, correct? A. Yes. MR. SLATER: Cheryll, could you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to decomposition yielding impurity, correct? A. To be precise MR. BALL: Objection. Asked and answered. A. Sorry, yeah. To be precise, the degradants that we discuss here or the document discuss here is typically related to after the making of a drug substance, okay. So once you have, you know, the final isolated pure drug substances that have met the your registered specifications, right, so from
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant carcinogenic risk. This group of high potency mutagenic carcinogens ('cohort of concern') comprises aflatoxin-like, N-nitroso-, and azoxy-compounds." Correct? A. Yes. Q. And the N-nitroso compounds include NDMA, correct? A. Yes. Q. And N-nitroso compounds include NDEA, correct? A. Yes. MR. SLATER: Cheryll, could you go to page 5, please? Thank you. You	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to decomposition yielding impurity, correct? A. To be precise MR. BALL: Objection. Asked and answered. A. Sorry, yeah. To be precise, the degradants that we discuss here or the document discuss here is typically related to after the making of a drug substance, okay. So once you have, you know, the final isolated pure drug substances that have met the your registered specifications, right, so from that point, okay, you will perform the
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant carcinogenic risk. This group of high potency mutagenic carcinogens ('cohort of concern') comprises aflatoxin-like, N-nitroso-, and azoxy-compounds." Correct? A. Yes. Q. And the N-nitroso compounds include NDMA, correct? A. Yes. Q. And N-nitroso compounds include NDEA, correct? A. Yes. MR. SLATER: Cheryll, could you go to page 5, please? Thank you. You can scroll up a little bit more. No,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to decomposition yielding impurity, correct? A. To be precise MR. BALL: Objection. Asked and answered. A. Sorry, yeah. To be precise, the degradants that we discuss here or the document discuss here is typically related to after the making of a drug substance, okay. So once you have, you know, the final isolated pure drug substances that have met the your registered specifications, right, so from that point, okay, you will perform the stability study, okay.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant carcinogenic risk. This group of high potency mutagenic carcinogens ('cohort of concern') comprises aflatoxin-like, N-nitroso-, and azoxy-compounds." Correct? A. Yes. Q. And the N-nitroso compounds include NDMA, correct? A. Yes. Q. And N-nitroso compounds include NDEA, correct? A. Yes. MR. SLATER: Cheryll, could you go to page 5, please? Thank you. You	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to decomposition yielding impurity, correct? A. To be precise MR. BALL: Objection. Asked and answered. A. Sorry, yeah. To be precise, the degradants that we discuss here or the document discuss here is typically related to after the making of a drug substance, okay. So once you have, you know, the final isolated pure drug substances that have met the your registered specifications, right, so from that point, okay, you will perform the stability study, okay. So based upon that, you know,
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	that perfect. Thank you. Q. At the end of that paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would theoretically be associated with a potential for a significant carcinogenic risk. This group of high potency mutagenic carcinogens ('cohort of concern') comprises aflatoxin-like, N-nitroso-, and azoxy-compounds." Correct? A. Yes. Q. And the N-nitroso compounds include NDMA, correct? A. Yes. Q. And N-nitroso compounds include NDEA, correct? A. Yes. MR. SLATER: Cheryll, could you go to page 5, please? Thank you. You can scroll up a little bit more. No, the other way. That should do it.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. A degradation pathway can also include decomposition of an ingredient in a manufacturing process well, rephrase. A degradation pathway can also well, rephrase. Degradation can also refer to decomposition yielding impurity, correct? A. To be precise MR. BALL: Objection. Asked and answered. A. Sorry, yeah. To be precise, the degradants that we discuss here or the document discuss here is typically related to after the making of a drug substance, okay. So once you have, you know, the final isolated pure drug substances that have met the your registered specifications, right, so from that point, okay, you will perform the stability study, okay.

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you know, degradation products.

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Or the same thing is true, you 3 know, once you formulate that already made, 4 you know, that drug substance into a finished 5 product, right, and so you're making a 6 finished or dosage form. So the degradants 7 or the degradation product, you know,

8 examination start from that point once you

9 make that product. So during the process something 11 will decompose, but, you know, it's -- it's 12 basically outside the scope of, you know, of 13 what this document is talking about. I would 14 believe, you know, when we're talking about, 15 you know, drug degradation is, you know, is 16 the -- these two scenarios that I just, you 17 know, described.

18 BY MR. SLATER:

19 Q. Looking at the paragraph --20 rephrase.

Looking at the first paragraph 22 under the heading "5.2. Degradants," the second sentence says, "Actual drug product degradation products include those observed

potential degradation products to be evaluated for mutagenicity," that's talking

about an assessment that's made to evaluate

Page 389

Page 390

potential risks, so you want to look for

those potential products of the degradation

process, correct?

7 MR. BALL: Objection.

8 Yes. Α.

9 Sorry.

BY MR. SLATER: 10

11 And that's something that's Q. evaluated when a risk assessment is performed on a manufacturing process, correct?

> Α. Right.

15 Q. And it talks about, in

16 performing that assessment, looking at

17 degradation chemistry principles, and that

18 would be looking at the science, right,

19 looking at the actual science of how these

20 substances may degrade, correct?

21 Yes, look at the science and 22 also the knowledge, yeah, knowledge being,

23 yeah, derived from science and, you know,

24 known to, you know, a specific group of the

above the ICH Q3B reporting threshold during 2 storage of the drug product in the proposed 3 long-term storage conditions and primary and secondary packaging." 4

5 That's what you were just talking about, right? 6

> Yes. Α.

Q. That's after the product has been manufactured and is now going to be stored and then it's going to be, I would assume, shipped and packaged, etcetera, 12 right?

13 Α. Exactly.

14 This says that the actual drug Q. product degradation products also include 15 those impurities that arise during the manufacture of the drug product, correct? 17

Let's see. Well, right here, 18

yeah, that's what it says. 19

20 And coming back now to the 21 paragraph second from the bottom of this 22 section, when it talks about "Knowledge of

relevant degradation pathways can be used to 23 23

24 help guide decisions on the selection of

communities like the process chemists.

For example, in the manufacture 3 of pharmaceutical drug substances such as valsartan, process chemists are part of that process to risk assess and evaluate based on science what are the potential degradation products of that manufacturing process, right?

8 9

2

7

15

Α. Yes.

10 Q. And it's required that that risk assessment be thorough and 11 scientifically based, for example, in 12 13 scientific literature, correct? 14

MR. BALL: Objection. Foundation, calls for a legal

16 conclusion. 17 To the scope, to the scope, you 18 know, because to the best knowledge of the

19 process science, you know, chemists, you

20 know, at that time.

21 BY MR. SLATER:

22 All right. We're going to come back to this, but I want to go through a 24 couple things first.

	PageID	: 82	142
	Page 391		Page 393
1	MR. SLATER: So the next thing	1	appreciably decomposed if allowed to stand
2	I'd like to do, Cheryll, is go to the	2	for several hours with solid KOH, NaOH or
3	next document, which I guess is	3	CaH2."
4	Exhibit311, which is the 1996	4	Do you see that?
5	textbook Purification of Laboratory	5	A. Mm-hmm.
6	Chemicals, please.	6	Q. And you would agree with me
7	(Whereupon, Exhibit Number	7	that from the perspective of the chemistry
8	ZHP-311 was marked for	8	community, the potential decomposition of DMF
9	identification.)	9	was something that was known and was known by
10	MR. SLATER: And this will be	10	mainstream chemists, correct?
11	Exhibit311. Thank you.	11	MR. BALL: Objection. Calls
12	BY MR. SLATER:	12	for speculation, expert testimony.
13	Q. Looking at Exhibit 311, this is	13	A. You know, this description did
14	a textbook titled Purification of Laboratory	14	not give specifics, okay. It's kind of a
15	Chemicals.		
16		15	and also, you know, here it says, you know,
	Do you see that? A. Mm-hmm.	16	if it's allowed, you know, to be in contact
17		17	with solid, you know, KOH, sodium chloride,
18	Q. And on the next page we can see	18	you know, you know, calcium hydride, these
19	that the date of publication was 1996.	19	are all very strong, you know, you know,
20	Do you see that?	20	base.
21	A. Mm-hmm.	21	BY MR. SLATER:
22	Q. And then it says it was	22	Q. It was understood, and this
23	reprinted multiple times, 1997, 1998, 1999,	23	we saw the dates before, that this was in
24	and 2000, correct?	24	print between 1996 and 2000, this textbook,
	Page 392		Page 394
1	A. Mm-hmm.	1	at least this version as of the time that
2	MR. SLATER: Cheryll, let's now	2	this rephrase.
3	scroll down to page 192, please. Down	3	A. Mm-hmm.
4	to the bottom of the page, the last	4	Q. This textbook documents
5	paragraph, please. Perfect.	5	scientific knowledge as of the late 1990s and
6	Q. I'm looking now at page 192,	6	2000 that DMF decomposes slightly at its
7	you can see that there's an entry for	7	normal boiling point to give small amounts of
8	"N,N-dimethylformamide," and then in	8	dimethylamine and carbon monoxide. That's
9	parentheses "DMF."	9	what's stated in that first sentence,
10	Do you see that?	10	correct?
11	A. Mm-hmm.	11	A. Mm-hmm.
12	Q. And DMF was one of the solvents	12	MR. BALL: Objection.
13	used as part of the zinc chloride process,	13	Objection. Mischaracterizes the
14	correct?	14	document, calls for expert testimony,
15	A. Yes.	15	and vague.
16	Q. And this indicates in this	16	•
			MR. SLATER: One second, I just
17	textbook that DMF "Decomposes slightly at its		want to get that down.
18	normal boiling point to give small amounts of	18	MR. BALL: And calls for
19	dimethylamine and carbon monoxide."	19	speculation.
20	Do you see that?	20	MR. SLATER: You said
21	A. Okay.	21	mischaracterizes the document, vague,
22	Q. And it says, "The decomposition	22	speculation.
23	is catalyzed by acidic or basic materials, so	23	MR. BALL: And expert
24	that even at room temperature DMF is	24	testimony.

	Pageid	<u>. 82</u>	.143
	Page 395		Page 397
1	MR. SLATER: Expert testimony.	1	correct?
2	BY MR. SLATER:	2	A. Well, what I'm just saying is
3	Q. That's what that sentence says,	3	that at the time of this process development,
4	correct?	4	it appears, you know, this minor
5	 A. That's what sentence says, yes. 	5	decomposition did not fall into the knowledge
6	Q. And in terms of scientific	6	base, you know, during that particular time
7	knowledge, as of the late 1990s and 2000s, it	7	period.
8	was known that DMF could decompose to give	8	Q. When you say "didn't fall into
9	off small amounts of dimethylamine, correct?	9	the knowledge base," you mean didn't fall
10	MR. BALL: Objection. Calls	10	into the knowledge base of the people at ZHP
11	for expert testimony, and speculation.	11	performing the risk assessment, correct?
12	A. So there is, yeah, this	12	A. It's not only the ZHP, you
13	description here, I mean, obviously. But,	13	know, because I believe that, you know, you
14	you know, based upon my understanding, you	14	know, this particular process is also
15	know, at the time of 2011 and 2012, you know,	15	utilized, you know, by other, you know,
16	there is no, like, patterns or specific	16	companies.
17	literatures indicating, you know, you know,	17	And also I would utilize you
18	you know, valsartan process chemistry	18	know, I would like to point out, you know,
19	utilizing DMF or, you know, slight amount of	19	some other companies, they use, you know, the
20	the impurity of DMF would you know, would	20	same zinc chloride process, but instead of
21	cause an issue.	21	utilizing, you know, DMF, you know, they use
22	So the bottom line is, you	22	another nitrogen-containing solvent, which is
23	know, there was a knowledge gap, you know,	23	NMP, you know, I guess we have discussed NMP
24	you know, at the time, and so	24	yesterday, you know, as like, you know, an
	Page 396		Page 398
1	Another thing is that	1	alternative sample diluent for the test base
2	basically, you know, everything, you know,	2	GMS.
3	can decompose to certain, you know, degree,	3	So for that process, similar
4	right, particularly, you know, under some	4	things happen, right, I mean retrospectively.
5	you know, by in contact with very strong	5	And so for the similar process, if you
6	base, you know, like, for example, here.	6	utilize NMP, then, you know, retrospectively
7	So when it's encountered with	7	now we know that NMP would also you know,
8	this, you know, you know, strong	8	during that process will decompose slightly,
9	base, you know, this would not be, you know,	9	and then during the quenching it would form,
10	relevant with the zinc chloride process.	10	you know, the other N-nitroso, you know,
11	So that process during that	11	compound. I think it's called an NMBA.
12	tetrazole formation, you know, you know, you	12	So, you know, basically, you
13	know, particular step during the reaction, it	13	know, you know, it you know, now
144	P. L. and C. and C. L. and Control of the Discourse of	مما	

14 did not use such a strong acid -- I'm sorry, 15 base, you know, KOH or, you know, sodium 16 hydride or whatever.

17 BY MR. SLATER:

18 You said something -- well, Q. 19 rephrase.

20 As part of the risk assessment, 21 the scientific analysis of the process 22 required that the potential decomposition of 23 DMF would be taken into account in the risk 24 assessment for the zinc chloride process,

16 minor decomposition of the solvent, you know, 17 did not fall into the knowledge base, you 18 know, of all of these process chemists. 19 When you said this information 20 about DMF decomposition to give off 21 dimethylamine was not within the knowledge 22 base specific to valsartan manufactured by 23 ZHP with the zinc chloride process, you were 24 referring to the knowledge base of ZHP,

14 retrospectively, you know, looking at the --

15 you know, this issue and certainly these

	<u>PageID</u>	<u>: 82</u>	144
	Page 399		Page 401
1	correct?	1	correct?
2	A. What I'm saying is it's not	2	MR. BALL: Objection.
3	only ZHP. You know, anyone utilizing, you	3	Mischaracterizes his earlier
4	know, the same or similar process, you know,	4	testimony, and mischaracterizes the
5	they had the same issue, now looking back.	5	document.
6	And also, you know, you know,	6	A. The sentence just says quite,
7	you know, in our process as well as, you	7	you know, vaguely, just said, you know, by
8	know, other, you know, you know, companies'	8	acidic or basic, right.
9	process, they have all been submitted, you	9	So it gives examples, specific
10	know, numerous times, you know, to the	10	examples of base, but here it didn't give
11	regulatory agencies, you know, you know,	11	specific examples of acids, right? I don't
12	different countries.	12	see any acids being mentioned here.
13	So prior to, you know,	13	BY MR. SLATER:
14	June 2018, you know, all of those, you know,	14	Q. Our jumping-off point to this
15	process chemists, you know, after, you know,	15	was the requirement under the ICH standard to
16	their regulatory review, they all get	16	apply degradation chemistry principles in
17	approved, you know, during that period.	17	order to perform a risk assessment. And
18	So basically, you know, I would	18	since ZHP was going to use DMF in the zinc
19	say, you know, it's fair to say, like, you	19	chloride process, they needed to do that
20	know, from FDA's, you know, you know, some of	20	analysis with regard to DMF, correct?
21	the document says, you know, during that time	21	A. You know, at the time of the
22	period the industry as well as regulators,	22	process development, okay, DMF was considered
23	you know, had a knowledge gap.	23	to be a very stable solvent, okay? And as a
24	Q. Certainly in the chemistry	24	matter of fact, you know, DMF is still, you
	Page 400		Page 402
1	community it was known that DMF could	1	know, from a process chemistry perspective in
2	decompose, give off small amounts of	2	general, is still a very stable solvent. It
3	dimethylamine, and that this could happen	3	all depends upon, you know, a particular
4	either in acidic or basic environments,	4	combination of you know, of different
5	correct?	5	facts, right?
6	That's what it says right	6	So with regard to the zinc
7	there, right?	7	chloride, you know, you know, process, either
8	MR. BALL: Hold on. Objection.	8	utilizing the DMF or like other company
9	Vague, calls for speculation, and	9	utilizing, you know, NMP, only when you, you
10	calls for expert testimony.	10	know, in that specific, you know, you know,
11	A. You know, basically, again, you	11	particular combination, now we know
12	know, as I said, here it says, you know, in	12	retrospectively, you know, that very tiny or
13	context with a, you know, strong base, it	13	low amount of decomposition would cause, you
14	will you know, it will decompose.	14	know, this problem. But otherwise, you know,
15	A lot of things, you know, a	15	it still would be fine.
16	lot of organic solvents, you know, if you	16	I mean, like our, you know,
17	treat it with strong base, you know, it would	17	newly, you know, improved process, right?
18	decompose. And, you know, it's all based	18	Once we, you know, found the root cause and
19	upon, you know, the context.	19	then we do the separate quenching, so we
20	BY MR. SLATER:	20	still using DMF right now.
21	Q. This says that the	21	And, you know, as I indicated,
22	decomposition of DMF is catalyzed by acidic	22	you know, yesterday, our valsartan now have,
23	or basic materials, and you agree with me it	23	you know, undetectable, you know, level of
24	can happen due to acidic or basic materials,	24	NDMA. You know, the detection limit is only

Page 403 5 ppb, which is, you know, 60 times lower 2 than the current FDA's requirement, which is

3 300 ppb. 4

7

13

Q. What is CaH2?

5 Α. Oh, that's calcium hydride.

6 Is that an acid? Q.

> No, that's a base. That's a Α.

8 very strong base.

9 Q. What is NaOH?

Sodium hydrochloride. Yeah. 10 Α. that's a very basic, you know, you know, you 11

know, base. Yeah. 12

I mean, I guess if somebody --14 I mean, like when I first learned chemistry. 15 sodium, you know, hydrochloride is probably 16 the first base that I learned.

17 Q. Coming back to my question, 18 in -- rephrase.

19

In performing its risk 20 assessment, ZHP was required to evaluate by applying degradation chemistry principles to 21

22 the potential degradation of DMF since it was 23 going to be used in the zinc chloride

24 process, correct?

Page 404

MR. BALL: Objection. Vague, 1

2 and asked and answered.

3 Based upon -- you know, based

4 upon what I know, okay, the original, you 5 know, you know, process chemist, okay, they

6 considered or they utilized this

7 degradation -- you know, you know, you know,

8 considering the degradation chemistry.

But the minor degradation of 9

10 DMF, it was just not falling to, you know,

11 the knowledge base. Not only with ZHP, as I

12 indicated; also with other companies utilize 13 the same or similar process.

14 So what that's supposed to mean

15 is that during that particular time period, 16 you know, within the process chemist, you

17 know, you know, circle, this was not a

18 concern, or this knowledge, you know, was not

19 there.

20 So that's what I meant, you

21 know. There was a knowledge gap, you know,

22 as indicated by, you know, some of those

23 FDA's training material.

24 BY MR. SLATER:

1 There was no knowledge gap

regarding the potential decomposition of DMF

to give off dimethylamine. That was

something that was known, and I'm showing you 4

a mainstream textbook that says it. That was

no secret, right? 6

MR. BALL: Objection.

8 Argumentative, speculative, and

9 mischaracterizes his testimony.

10 Look, chemistry as well as all

of the other sciences, I mean, it's -- you 11

12 know, it has enormous details in terms of the

knowledge, okay. And now, you know, we

looking back, you know, the critical thing is

15 that, you know, someone, or a group of people

16 or regulators, you know, you know, need to

17 connecting those dots, they scattered, you

know, you know, here and there. Otherwise,

19 you know, yeah, I mean these piece of

knowledge, you know, could be here and there, 20

21 right.

22 I mean, when we, you know, come

23 up with a solution or finding, you know,

24 people, you know, very often can go back and

Page 406

Page 405

then now realize, you know, oh, yeah, if you

2 were to connecting these dots, you know, 3 together at the time, you know, you may, you

4 know, you know, avoid, you know, that issue.

5 But, you know, but that's also,

you know, part of the, you know, knowledge

7 base, right. Not only we talking about the 8 individual pieces knowledge here and there,

you know, also you need to, you know, 9

making -- you know, you know, connecting the

11 dots.

12 So that's another level, you

know, of the knowledge. And, you know, so 13

14 that's what I, you know, meant, you know,

specifically with regard to this issue, you 15

16 know. It is -- nobody, you know, throughout

17 industry as well as the regulator, you know,

18 at the time, you know, were able to

connecting all the dots. 19

20 BY MR. SLATER:

21 And my questions are specific 22

to the people who worked at ZHP when the zinc

23 chloride process was being developed. Those

people who were in charge of that process 24

PageID: 82146 Page 407 1

- 1 needed to perform a risk assessment that
- 2 included evaluating the potential
- 3 decomposition of DMF as part of that process,
- 4 it's something that had to be considered,
- 5 correct?
- 6 Α. As I told you, you know, also
- 7 if you look at some of the FDA's, you know,
- you know, released documents, you need to
- 9 have that knowledge, or you need to have the
- 10 knowledge, you know, to connecting, you know,
- those dots, you know, otherwise, you know, 11
- 12 you would have a knowledge gap.
- Once you had that knowledge 13
- 14 gap, you -- you know, it will not lead you to
- 15 that direction. But as I said, in general
- 16 during the, you know, process development,
- 17 ZHP's, you know, process chemists look at
- 18 the, you know, the degradation issues.
- 19 But as I said, you know, due to
- the knowledge gap, it just didn't lead them, 20
- you know, to this particular issue. 21
- Did you just say that ZHP's 22
- 23 process chemists looked at the degradation
- issues as part of the process change? 24
- Page 408
- 1 A. Well, based upon, you know, you
- know, you know, maybe some of the documents,
- 3 it's probably there. But although I, you
- 4 know, didn't have time, you know, you know,
- 5 you know, to go through them in very -- you
- know, in full details.
- 7 Q. You have no idea if that was
- 8 looked at, right?
- 9 A. I had some idea, but I said
- I -- you know, I'm not a process chemist, you
- 11 know, so it's better to be answered by a
- process chemist. 12
- Well, with regard to the root 13
- 14 cause investigation which would have included
- evaluating how this happened, did you see
- 16 anything indicating that anybody at ZHP
- 17 considered the potential decomposition of the
- DMF to yield dimethylamine as part of the
- process? Did you see anything indicating
- that anybody thought about that at all at 20
- ZHP? 21
- 22 Α. Basically as I already said,
- you know, due to the knowledge gap this
- particular issue was not considered.

Page 409 And that knowledge gap would Q.

- include a lack of research in either
- textbooks or published literature, in the
- scientific literature, to evaluate potential
- decomposition of DMF? It wasn't researched 5
- at all, correct? 6

7

8

9

10

22

6 7

9

24

MR. BALL: Objection.

Foundation, speculation.

Go ahead and answer if you can.

Yeah, I think that's -- that's

a speculation. You know, that process was 11

developed very early on, you know. I was not 12

there, I am not a process chemist, so I 13

cannot speculate.

15 BY MR. SLATER:

16 Q. You've seen nothing indicating

17 that anybody at ZHP made any effort to look

18 at any scientific literature or publications

19 at all to evaluate potential decomposition of

20 DMF, you've seen nothing indicating anyone

21 looked at that, correct?

MR. BALL: Objection.

23 Compound.

24 Go ahead and answer if you can.

Page 410

As I said, I cannot answer that 1 A. 2 question, because I was not there, you know,

I'm not a process chemist.

BY MR. SLATER: 4

5 In your role as a 30(b)(6) --Q.

MR. BALL: Hold on, hold on.

Either you've seen it or you haven't

seen it. 8

> I haven't seen it, yeah. Α.

10 MR. BALL: Yeah, that's fine.

BY MR. SLATER: 11

And coming back to the ICH 12 Q.

guideline, evaluation of the degradation 13

chemistry principles would have required an

evaluation of scientific literature or 15

publications to try to answer that question, 16 17 right?

MR. BALL: Objection. 18

Mischaracterizes the guideline. 19

20 Yeah, the guideline has that

information. Yeah. 21

MR. SLATER: Let's take this 22 23 exhibit down and go to Exhibit 197.

MR. BALL: Why don't we take --

	<u>PageID</u>	<u>: 82</u>	147
	Page 411		Page 413
1	we've gone about an hour 15 since our	1	Q. Sure. I think you're probably
2	last break	2	right, actually.
3	MR. SLATER: We can take this	3	A. 32. Yeah, Purification of
4	down and take a break now.	4	Laboratory Chemicals, 19 well, it's 1966.
5	MR. BALL: Okay.	5	Okay, yeah, that's looks like that's the
6	MR. SLATER: Take this down,	6	same one, yes.
7	and let's go off the record.	7	MR. SLATER: Let's stay on that
8	MR. BALL: Okay. Great.	8	page, Cheryll.
9	Thanks.	9	Q. So reference 32 is to the
10	THE VIDEOGRAPHER: The time	10	textbook that we were talking about a moment
11	right now is 9:46 a.m. We're now off	11	ago, Exhibit311, except this is a citation
12	the record.	12	to the version of that textbook published in
13	(Whereupon, a recess was	13	1966, correct?
14	taken.)	14	A. Looks like, yes, mm-hmm. It
15	THE VIDEOGRAPHER: The time	15	looks like the first version, right?
16	right now is 10:04 a.m. We're back on	16	Q. I don't know.
17	the record.	17	A. Probably, yeah.
18	BY MR. SLATER:	18	Q. So this article is showing that
19	Q. On the screen we have	19	a textbook actually talked about the
20	Exhibit 197, which is an article that was	20	decomposition of DMF to yield dimethylamine
21	published in scientific literature in 2009	21	going back as far as 1966, correct?
22	titled "N,N-Dimethylformamide: much more than	22	A. Yes.
23	a solvent."	23	MR. SLATER: Let's take that
24	Do you see that?	24	down now, and then go to Exhibit 211.
	Page 412		Page 414
1	A. Mm-hmm.	1	Q. Exhibit 2 rephrase.
2	A. Mm-hmm. MR. SLATER: Let's go, if we	2	Q. Exhibit 2 rephrase. Exhibit 211 is an article that
2 3	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand	2	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of
2 3 4	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent.	2 3 4	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is
2 3 4 5	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source	2 3 4 5	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of
2 3 4 5 6	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF	2 3 4 5 6	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from
2 3 4 5 6 7	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF decomposes slightly at its boiling point to	2 3 4 5 6 7	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Triethylamine."
2 3 4 5 6 7 8	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide,	2 3 4 5 6 7 8	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Triethylamine." Do you see that?
2 3 4 5 6 7 8 9	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room	2 3 4 5 6 7 8 9	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Triethylamine." Do you see that? A. Mm-hmm.
2 3 4 5 6 7 8 9	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room temperature in the presence of some acidic or	2 3 4 5 6 7 8 9 10	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Triethylamine." Do you see that? A. Mm-hmm. Q. And it looks like this was
2 3 4 5 6 7 8 9 10	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room temperature in the presence of some acidic or basic materials. This observation has led to	2 3 4 5 6 7 8 9 10 11	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Triethylamine." Do you see that? A. Mm-hmm. Q. And it looks like this was submitted in 2009 and published in 2010,
2 3 4 5 6 7 8 9 10 11 12	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room temperature in the presence of some acidic or basic materials. This observation has led to the use of DMF as a carbonylating agent."	2 3 4 5 6 7 8 9 10 11	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Triethylamine." Do you see that? A. Mm-hmm. Q. And it looks like this was submitted in 2009 and published in 2010, correct?
2 3 4 5 6 7 8 9 10 11 12 13	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room temperature in the presence of some acidic or basic materials. This observation has led to the use of DMF as a carbonylating agent." Do you see that?	2 3 4 5 6 7 8 9 10 11 12 13	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Triethylamine." Do you see that? A. Mm-hmm. Q. And it looks like this was submitted in 2009 and published in 2010, correct? A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room temperature in the presence of some acidic or basic materials. This observation has led to the use of DMF as a carbonylating agent." Do you see that? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Triethylamine." Do you see that? A. Mm-hmm. Q. And it looks like this was submitted in 2009 and published in 2010, correct? A. Yes. Q. And the people who published
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room temperature in the presence of some acidic or basic materials. This observation has led to the use of DMF as a carbonylating agent." Do you see that? A. Yes. Q. So this is another example of	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Triethylamine." Do you see that? A. Mm-hmm. Q. And it looks like this was submitted in 2009 and published in 2010, correct? A. Yes. Q. And the people who published this article, it looks like Zhi Sun, Yong
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Mm-hmm. MR. SLATER: Let's go, if we could, to page 8315, the right-hand column, 3. Excellent. Q. Heading Number 3 says, "Source of carbon monoxide," and then it says, "DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room temperature in the presence of some acidic or basic materials. This observation has led to the use of DMF as a carbonylating agent." Do you see that? A. Yes. Q. So this is another example of an article in the published literature	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Exhibit 2 rephrase. Exhibit 211 is an article that was published in 2010 in the Journal of Physical Chemistry, and the title is "Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Triethylamine." Do you see that? A. Mm-hmm. Q. And it looks like this was submitted in 2009 and published in 2010, correct? A. Yes. Q. And the people who published this article, it looks like Zhi Sun, Yong Dong Liu, and Ru Gang Zhong from the College
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	14	me that in performing the risk assessment at	14	amount of dimethylamine.
16. the process chamiete of 7HD would have known 140. Fave to also that is the first of the process of the proc	15	the outset with the zinc chloride process,	15	Second of all, you know, you
To the process chemists at ZmP would have known 16 have to also link, you know, its reaction	16	the process chemists at ZHP would have known	16	have to also link, you know, its reaction
17 through degradation chemistry principles and 17 with the nitrous acid. So it's basically,	17	through degradation chemistry principles and	17	with the nitrous acid. So it's basically,
18 the principles here in this article that NDMA 18 you know, you know, you need, or someone at	18	the principles here in this article that NDMA	18	you know, you know, you need, or someone at
19 could form if they had gone through 19 the time, you know, need to connecting the	19	could form if they had gone through	19	the time, you know, need to connecting the
20 literature, as we just did, correct? 20 dots, right?	20	literature, as we just did, correct?	20	dots, right?
MR. BALL: Objection. 21 I mean, a lot of things, you	21	MR. BALL: Objection.	21	I mean, a lot of things, you
22 Speculative. 22 know, looking retrospectively it may become,	22	Speculative.	22	know, looking retrospectively it may become,
A. I mean, this is basically, you 23 you know, much more obvious. But at the			23	•
24 know, the same kind of question, I mean, you 24 time, as I indicated before, you know, the	24	know, the same kind of question, I mean, you	24	time, as I indicated before, you know, the

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minor decomposition of DMF, it was just not, 2 you know, you know, falling into the

3 knowledge base.

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4 BY MR. SLATER:

> Q. If ZHP's process team -rephrase.

If the people at ZHP had performed a proper risk assessment and actually looked at the scientific literature, this article was there to be found in 2011, correct?

12 A. Again, as I indicated, you know, chemistry is a vast, you know, you 13 know, you know -- as a science contains vast. you know, you know, knowledge base. 15

And as I indicated also, you 17 know, a lot of things looking back, you know, 18 you know, people would then start to 19 connecting all the dots. So the knowledge 20 base is not only, you know, you know, the 21 individual pieces, you know. Also somebody 22 at some time or at the right time need to 23 connecting those dots.

So another thing is, as I

scientific analysis to connect the dots.

That's the point of a risk assessment, to do

Page 421

a thorough scientific analysis and connect

the dots, correct? 4

5 Α. The thorough scientific evaluation would be limited at any given 6

time, okay, to a particular, you know, set of 7

8 knowledge.

9 I mean, you know, you basically 10 just, you know, cannot, you know, you know, go through, you know, every single details. 11

12 I mean, it's just not practical, you know.

Unless -- unless, like, if

13 14 something happened, you know, for example

15 like these particular events, right? Now

16 everybody, you know, you know, start to

connecting the dots, and then, you know, 18 regulatory agencies, you know, also require

19 every company to do, you know, you know, you 20 know, you know, the risk assessment,

particularly with regard to the nitrosamine, 21

22

you know, you know, potential risk, right. 23 And then, you know, now we see

24 more and more, you know, you know, different

Page 420

indicated before, you know, not only, you

know, ZHP, but also other company utilizing, 2

3 you know, the same or similar, you know, you

4 know, a certain process, a similar case

5 being -- you know, utilizing NMP as the 6 reaction solvent.

You know, those processes, they 8 were all commercialized. They were all previously submitted to various regulatory 10 agencies, including European agencies, you 11 know, the FDAs.

And so at the time, you know, 13 again, you know, at these agencies, you know, 13 there are, you know, great numbers of 15 capable, you know, scientists.

So, you know, it appears now retrospectively it also did not -- you know, 17 18 you know, I mean, they obviously also, you know, seem to have, you know, the knowledge19 19 gap particularly, you know, connecting the 21 dots.

22 When you refer to "connecting" Q. 23 the dots" -- rephrase. 24

A risk assessment requires a

Page 422 commercialized drugs, you know, you know, you

2 know, being -- having the issue of NDMA,

3 right.

14

4 As I mentioned yesterday, we

have seen issues for NDMA in, you know, 5

ranitidine, you know, and as I said that, you

know, ranitidine has become a commercialized 7

8 product, I think as early as 1981.

9 And, you know, you know, these

companies, you know, you know, this 10

11 particular product, you know, it was

12 developed by, you know, this very well-known,

you know, GlaxoSmithKline in the company.

And also during the course of

15 this very long history, we also see other

companies, you know, including Sanofi, you

know, which is, you know, also another very

18 famous, you know, France-based multinational

pharmaceutical company, right, they also

20 manufacture, you know, you know, you know,

21 ranitidine for quite a few years.

22 You know, I'm sure, you know,

23 their scientists as well as, you know, the

early, you know, you know, GSK or, you know,

	<u>PageID</u>	: 82	150
	Page 423		Page 425
1	French, you know, SmithKline at the time,	1	that you need to, you know, you know, at the
2	they all did a, you know, risk assessment	2	same time you're controlling the costs, you
3	based on the best knowledge at that time.	3	need to also develop a product, right, which
4	But still, you know, this issue	4	is comparable you know, like during the
5	remained, you know, unknown until, you know	, 5	process change, you know, which is comparable
6	these particular events become known, you	6	to the previous, you know, product. So based
7	know, to, you know, everybody.	7	upon my limited knowledge, you know, at the
8	Q. Am I correct that the only	8	time of the process development during that
9	company that was selling ZHP valsartan API -	- 9	evaluation.
10	rephrase.	10	So the overall quality, you
11	Am I rephrase.	11	know, of this zinc chloride process was
12	ZHP was selling its zinc	12	comparable, you know, to the previous ones.
13	chloride process valsartan rephrase.	13	MR. SLATER: Cheryll, let's go
14	ZHP developed the zinc chloride	14	t o Exhibit 213, please. 213.
15	process in order to sell zinc chloride	15	MR. BALL: Adam, can we go off
16	process valsartan for profit by ZHP. That	16	for just one second while I go ask the
17	was the purpose of that, correct?	17	people out in the hall to be a little
18	MR. BALL: Objection. Outside	18	bit more quiet?
19	the scope.	19	MR. SLATER: Sure.
20	A. Again, you know, first of all,	20	MR. BALL: Thank you. I'll be
21	you know, I'm not a process chemist, okay,	21	
22	but if you want to ask, you know, my	22	right back.
23	personal, you know, you know, perspective,	23	MR. SLATER: Let's go off the
24			record.
24	you know, I might give you one, okay?	24	THE VIDEOGRAPHER: The time
١.	Page 424	١.	Page 426
1	Every first of all, every	1	right now is 10:23 a.m. We're now off
2	commercial process, you know, you need to	2	the record.
3	consider costs, right? Result in effective	3	(Pause.)
4	costs, you know, we would have had a lot of	4	THE VIDEOGRAPHER: The time
5	issues, right?	5	right now is 10:23 a.m. We're back on
6	And the reason, you know, you		
7		6	the record.
	know I mean, the United States has the	6 7	BY MR. SLATER:
8			
8	know I mean, the United States has the	7	BY MR. SLATER:
_	know I mean, the United States has the best, you know, generic drug company or	7 8	BY MR. SLATER: Q. We're back in Exhibit 213, the
9	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world,	7 8 9	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the
9 10	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you	7 8 9 10	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA.
9 10 11	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know,	7 8 9 10 11	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you
9 10 11 12	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously.	7 8 9 10 11 12	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please?
9 10 11 12 13	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously. So, you know, controlling	7 8 9 10 11 12 13	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please? Middle of the page, please, a little
9 10 11 12 13 14	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously. So, you know, controlling costs, you know, you know, is something every	7 8 9 10 11 12 13 14	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please? Middle of the page, please, a little further down. Okay.
9 10 11 12 13 14 15	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously. So, you know, controlling costs, you know, you know, is something every company, you know, whether, you know, it's a	7 8 9 10 11 12 13 14 15	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please? Middle of the page, please, a little further down. Okay. Q. This is the FDA's commentary on
9 10 11 12 13 14 15 16	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously. So, you know, controlling costs, you know, you know, is something every company, you know, whether, you know, it's a generic drug company or a multinational	7 8 9 10 11 12 13 14 15 16	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please? Middle of the page, please, a little further down. Okay. Q. This is the FDA's commentary on this subject we've been discussing, and it
9 10 11 12 13 14 15 16 17	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously. So, you know, controlling costs, you know, you know, is something every company, you know, whether, you know, it's a generic drug company or a multinational pharmaceutical company, you know, everybody,	7 8 9 10 11 12 13 14 15 16 17	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please? Middle of the page, please, a little further down. Okay. Q. This is the FDA's commentary on this subject we've been discussing, and it says, "You also failed to evaluate the need
9 10 11 12 13 14 15 16 17 18	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously. So, you know, controlling costs, you know, you know, is something every company, you know, whether, you know, it's a generic drug company or a multinational pharmaceutical company, you know, everybody, you know, you know, doing that, right. And also by controlling costs a	7 8 9 10 11 12 13 14 15 16 17	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please? Middle of the page, please, a little further down. Okay. Q. This is the FDA's commentary on this subject we've been discussing, and it says, "You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were
9 10 11 12 13 14 15 16 17 18	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously. So, you know, controlling costs, you know, you know, is something every company, you know, whether, you know, it's a generic drug company or a multinational pharmaceutical company, you know, everybody, you know, you know, doing that, right. And also by controlling costs a company would also, you know, share, you	7 8 9 10 11 12 13 14 15 16 17 18	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please? Middle of the page, please, a little further down. Okay. Q. This is the FDA's commentary on this subject we've been discussing, and it says, "You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your
9 10 11 12 13 14 15 16 17 18 19 20 21	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously. So, you know, controlling costs, you know, you know, is something every company, you know, whether, you know, it's a generic drug company or a multinational pharmaceutical company, you know, everybody, you know, you know, doing that, right. And also by controlling costs a company would also, you know, with patients,	7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please? Middle of the page, please, a little further down. Okay. Q. This is the FDA's commentary on this subject we've been discussing, and it says, "You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process
9 10 11 12 13 14 15 16 17 18 19 20 21 22	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously. So, you know, controlling costs, you know, you know, is something every company, you know, whether, you know, it's a generic drug company or a multinational pharmaceutical company, you know, everybody, you know, you know, doing that, right. And also by controlling costs a company would also, you know, share, you know, those savings, you know, with patients, right?	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please? Middle of the page, please, a little further down. Okay. Q. This is the FDA's commentary on this subject we've been discussing, and it says, "You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change."
9 10 11 12 13 14 15 16 17 18 19 20 21	know I mean, the United States has the best, you know, generic drug company or industry, you know, you know, in the world, you know. That has bring down, you know, you know, the cost to the patients, you know, tremendously. So, you know, controlling costs, you know, you know, is something every company, you know, whether, you know, it's a generic drug company or a multinational pharmaceutical company, you know, everybody, you know, you know, doing that, right. And also by controlling costs a company would also, you know, with patients,	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. SLATER: Q. We're back in Exhibit 213, the November 29, 2018 warning letter from the FDA. MR. SLATER: Cheryll, would you go to page 4 of that document, please? Middle of the page, please, a little further down. Okay. Q. This is the FDA's commentary on this subject we've been discussing, and it says, "You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process

	PageID	: 82	151
	Page 427		Page 429
1	process, correct?	1	actually I want to withdraw that and actually
2	A. Let me see.	2	go back to my question.
3	MR. BALL: Objection. Calls	3	You agree with me that ZHP was
4	for speculation.	4	responsible during the process change to
5	A. It looks like so, mm-hmm.	5	develop and use suitable methods to detect
6	BY MR. SLATER:	6	impurities when developing and making changes
7	Q. Then the FDA says, "You are	7	to the manufacturing process, correct?
8	responsible for developing and using suitable	8	MR. BALL: Objection.
9	methods to detect impurities when developing,	9	Mischaracterizes his earlier
10	and making changes, to your manufacturing	10	testimony.
11	processes. If new or higher levels of	11	A. You know, as I as I said, I
12	impurities are detected, you should fully	12	already answered this question before, you
13	evaluate the impurities and take action to	13	know, because there is, you know, like FDA,
14	ensure the drug is safe for patients."	14	you know, you know, the statement says, you
15	You agree with what the FDA	15	know, it said if new or higher level of
16	said in terms of what the obligations of ZHP	16	impurity are detected.
17	were? That's an accurate statement, correct?	17	But as I said, you know, the
18	MR. BALL: Objection. Calls	18	GC-FID method, which is the residual solvent
19	for a legal conclusion.	19	method and also is a registered, you know,
20	A. The last sentence sorry,	20	method, okay, it just not capable, you know,
21	yeah.	21	detecting NDMA.
22	The last sentence said, "If new	22	As far as, you know, you know,
23	or higher level of impurity are detected."	23	go back to the, you know, the very same, you
24	But this was not the case with NDMA, because	24	know, point, you know, right, basically, you
		24	
١,	Page 428	١,	Page 430
1	as I indicated, you know, the residual	1	know, I said during the time of the process
2	solvent method is not capable to detect NDMA.	2	change, you know, no one, you know, the
3	BY MR. SLATER:	3	industry, also the regulatory agencies, you
4	Q. GC-MS was capable of detecting	4	know, you know, had that knowledge gap.
5	and identifying NDMA if you thought about it	5	You know, if at the time, you
6	and looked for it, right?	6	know, people already knew, like today, yeah,
7	A. The GC	7	everybody will go that extra mile and to,
8	MR. BALL: Hold on, hold on.	8	you know, look for it. But, you know, that
9	Objection. Calls for expert	9	was just not the case during that time.
10	testimony, argumentative, and	10	BY MR. SLATER:
11	mischaracterizes his testimony.	11	Q. Looking now at the third full
12	Go ahead.	12	paragraph on page 4 of this FDA warning
13	A. I think I, you know, answered	13	letter of November 29, 2018, the FDA stated,
14	it yesterday. The GC-MS method are based	14	"Your response states that predicting NDMA
15	upon the ZHP's GC-FID method, okay, is still	15	formation during the valsartan manufacturing
16	not, you know, you know, as is it's	16	process required an extra dimension over
17	still not adequately to detect NDMA as you	17	current industry practice, and that your
18	know, as a suitable, you know, analytical	18	process development study was adequate. We
19	control method.	19	disagree. We remind you that common industry
20	BY MR. SLATER:	20	practice may not always be consistent with
21	Q. If ZHP had been looking for	21	cGMP requirements and that you are
22	NDMA or any nitrosamines with GC-MS well,	22	responsible for the quality of drugs you
23	I'll withdraw that.	23	produce."
24	The problem ultimate well,	24	Do you see that?

PageID: 82152 Page 433 Page 431 1 Α. Yeah, I see that, mm-hmm. failure to adequately assess the risks, but 2 Q. And you understand that ZHP at somebody else is responsible for ZHP's 3 all times was required to comply with cGMP failures? requirements with regard to its process for 4 A. Again -manufacturing its valsartan that it was going 5 MR. BALL: Objection. to sell. You agree with that, correct? 6 Mischaracterizes his testimony. 6 7 7 MR. BALL: Objection. Calls Again, you know, this is not 8 for a legal conclusion. what I'm saying, okay. BY MR. SLATER: 9 To me it's very obvious, you 9 know, this whole paragraph is a Well, who's responsible for the 10 10 Q. retrospective, you know, statement. So going 11 inadequate risk assessment? Is it ZHP, or is 11 12 back to that, you know, period, you know, 12 it someone else? 13 we -- as I said, you know, we did all what we MR. BALL: Objection. 13 14 can do, and we filed to the various 14 Foundation and compound. 15 regulatory agencies like everybody else. And 15 When FDA says, you know, there 16 this process, you know, was approved by was a knowledge gap at the time for both 16 17 multiple, you know, regulatory agencies, industry as well as for the regulatory 17 18 including the FDA. agencies, you tell me who would be 18 19 And also, as I said, you know, 19 responsible. 20 I indicated that, you know, in some of the 20 BY MR. SLATER: 21 most recently released FDA training material, 21 If you look at this letter from 22 you know, FDA, you know, basically 22 the FDA in November of 2018, the last part of 23 acknowledged, you know, the knowledge gap 23 that paragraph we've been talking about says, 24 during the previous time by both industry as "You are responsible for the quality of drugs 24 Page 434 Page 432 well as regulators. you produce." 2 BY MR. SLATER: 2 You agree with that statement, So is it ZHP's position that 3 3 Q. correct? 4 other companies or regulatory agencies are at 4 MR. BALL: Objection. Calls 5 fault for letting ZHP manufacture valsartan 5 for a legal conclusion. 6 with the zinc chloride process and not Go ahead. 6 7 adequately evaluate and realize that NDMA 7 Yes. Everybody, or every Α. manufacturer will be responsible to the 8 could be produced? Are you saying it's someone else's fault and it's not ZHP's 9 9 extent, you know, you know, with their best 10 responsibility? 10 efforts at the time. 11 MR. BALL: Objection. 11 BY MR. SLATER: Foundation, mischaracterizes his And ZHP is -- rephrase. 12 12 Q. 13 earlier testimony. 13 ZHP is also responsible for its It's clearly not what I said failure to disclose to the FDA in 2017 when 14 15 before. Okay. What I'm saying or what I it knew at the latest -- rephrase. Let me --15 have been saying is during that particular let me reask the question. 16 16

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22

FDA, right?

time the industry as well as the regulatory 17 agency had that knowledge gap. Okay. And 19 also, you know, science, you know, is making

progress all the time. 20

21 BY MR. SLATER:

Are you -- rephrase. 22 Q. 23

Speaking for ZHP right now, is 24 ZHP saying ZHP is not responsible for its 23 MR. BALL: Objection. 24 Foundation, calls for a legal

And ZHP as of July 2017 at the

latest, when it knew that NDMA had been

produced as part of the zinc chloride process

and was an impurity in its valsartan, at that

point ZHP had a responsibility to tell the

	PageID	<u>: 82</u>	153
	Page 435		Page 437
1	conclusion.	1	identification.)
2	A. I think I you know, as I	2	BY MR. SLATER:
3	told you before, at the time it was, you	3	Q. Looking at Exhibit312, this is
4	know, it was a guess, you know, by a single,	4	the July 23, 2018 Establishment Inspection
5	you know, chemist.	5	Report.
6	BY MR. SLATER:	6	You're familiar with this
7	Q. That single chemist was	7	document, right?
	Jinsheng Lin who worked for you, right?	8	
8	•		'
9	A. He was in my department, yes.	9	through this, yeah.
10	Q. He's still in your department,	10	MR. SLATER: Let's go, if we
11	right?	11	could, to page 25, Cheryll, 25 of 58.
12	A. He still is, yes.	12	The Bates number, the last two digits
13	Q. Did Jinsheng Lin tell you	13	are 73. Perfect.
14	rephrase.	14	Q. You mentioned earlier that the
15	Did rephrase.	15	process change to zinc chloride took into
16	Did Jinsheng Lin show you the	16	account cost. Remember you were telling me
17	chromatograms that he used to identify the	17	that earlier?
18	NDMA in the valsartan?	18	MR. BALL: Objection.
19	MR. BALL: Objection.	19	Mischaracterizes his earlier
20	Foundation.	20	testimony.
21	A. As I told you, you know, in	21	A. You mean, you know, why, you
22	that e-mail clearly, you know, he's just	22	know, a new process like zinc chloride
23	making a you know, a guess or, you know, a	123	process was developed, right?
24	projection, you know.	24	. ///
	Page 436		Page 438
1	BY MR. SLATER:	1	BY MR. SLATER:
2	Q. Well, actually, what he said in	2	Q. Didn't you tell me earlier that
3	that e-mail was that NDMA occurs in valsartar		one of the benefits well, rephrase.
4	when it's quenched with sodium nitrite, which	4	Didn't you tell me earlier you
5	was an accurate statement. It was		have to take into account the cost?
6	scientifically accurate, correct?	6	A. Oh, yeah, yeah. Yeah, every
7	MR. BALL: Objection. Vague,	7	process, you know, development, yeah, cost,
8	and mischaracterizes the document.	8	you know, is a factor to be, you know, to be
9	A. As I said, again, you know,	9	considered.
10	this was his projection.	_	
11	MR. SLATER: Cheryll, let's go,	10	But also that I mentioned, you
	if we could, to that other document	11	know, very clearly, you know, that the
12	,	12	fundamental, you know, you know, you know,
13	you started to pull up. I don't	13	factor that need to be considered is, you
14	remember what it was previously marked	14	know, the product produced by the new process
15	as, if you could tell us. The	15	need to be comparable with regard to the
16	establishment inspection report.	16	registered specifications.
17	MS. CALDERON: I don't think it	17	Q. Well, let's look at
18	was previously marked.	18	rephrase.
19	MR. SLATER: Oh, really? Well,	19	Looking at the middle paragraph
20	we can mark it again. What are we up	20	on this page, there is a statement in the
21	to? I'm not the guy to know that	21	middle after the second line rephrase.
22	answer.	22	Looking at the center
22	(Whereupon, Exhibit Number	23	rephrase.
23	· ·		•
23 24	ZHP-312was marked for	24	Looking at the paragraph in the

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middle of the page, the second sentence says,

"Mr. Jun Du, Executive Vice President,

apologized and stated the change control

4 should have stated the purpose of the change5 was to save money."

6 A. I'm sorry. Where it is?

Q. Sure.

8 Let's do this. Looking at the

9 carryover paragraph at the top of the page,

10 you can see that it's discussing, about four

11 lines from the bottom, the "Valsartan

12 Process II Zinc Chloride Process Change

13 Summary."

7

16

2

4

16

18

14 Do you see that?

15 A. Wait a second.

So basically it's the first

17 paragraph, right?

18 Q. Right. Four lines from the

19 bottom of that paragraph.

A. Four lines from the bottom.

21 One, two... Four lines. One, two, three...

22 I don't see "Mr. Jun Du" here.

23 Q. No. Now I'm on a different

24 paragraph. I'm leading into it now. So let

ays, 1 Q. Right. The first paragraph,

1 Q. Right. The first paragraph, 2 four lines from the bottom of the first

3 paragraph, it's discussing the zinc chloride

Page 441

Page 442

4 process change.5 Do vou s

Do you see that?

6 A. Hold on. So four line from the 7 bottom of the first paragraph.

8 And also, yeah, going above,

9 like, Mr. Dong pointed out a table

0 describing, right, manufacturing process for

11 valsartan API.

"Mr. Dong pointed to a tabledescribing manufacturing operating ranges in

14 Valsartan Process II Zinc Chloride Process

15 Change Summary."

And then, "The table does not

17 include an acceptance criteria. I asked

18 Mr. Dong if the firm established specific

19 parameters with acceptance criteria which the

20 firm used to evaluate if the isomer

21 conversion was reduced and the yield

22 increased...again pointed to the same table."

Okay. Yeah, so there's some,

24 yeah, discussion with Mr. Peng Dong, yes.

Page 440

1 me as you this.

If you look at the first

3 paragraph --

A. Oh. Oh, actually, I'm sorry.

5 Actually I see in the second paragraph, okay.

6 Second paragraph, yeah, "Mr. Jun Du,

7 Executive Vice President, apologized and

8 stated that the change control should have

9 stated the purpose" of change -- "should have

10 stated the purpose was to save money."

11 I don't know -- I don't know,

12 you know, you know, what that's supposed to

13 mean. Maybe --

MR. BALL: He hasn't asked you

15 a question yet.

Go ahead, Adam.

17 BY MR. SLATER:

Q. In this Establishment

19 Inspection Report, you can see at the first

20 paragraph it's discussing the zinc chloride21 process change.

22 Do you see

Do you see that?

A. You mean the very first paragraph, right?

1 Okay.

5

9

Q. In the first paragraph, we can
see the process change to the zinc chloride
process is being discussed, correct?

A. You're basically again talking about the first paragraph?

6 about the first paragraph?
7 Q. Right. It's discussing the
8 zinc chloride process change, correct?

A. Yes. So far the very first

10 line of the first paragraph, right, okay? It

11 says, okay, "Change Request...did not

12 identify specific parameters the firm would

13 use to evaluate the effectiveness of the

14 requested change and the impact of the

15 requested change on intermediates and/or the

16 final valsartan API prior to implementing17 change..."

So it's talk about particularly change request here.

Q. And then in the second

21 paragraph on this page, in the second line it

22 says that "Mr. Jun Du, Executive Vice

23 President, apologized and stated the change control should have stated the purpose of the

	PageiD	. 0_	100
١.	Page 443		Page 445
1	change was to save money. Mr. Du further	1	MR. BALL: Objection.
2	stated the cost reduction was so significant	2	Foundation, mischaracterizes his
3	it is what made it possible for the firm to	3	earlier testimony, and outside the
4	dominate the world market share."	4	scope.
5	Do you see what I just read?	5	 A. I would say that's your
6	A. I don't know what you know,	6	speculation.
7	you know, what he actually said	7	BY MR. SLATER:
8	MR. BALL: That's a yes-or-no	8	Q. And then in April 2018, when
9	question, did you see what he read.	9	you directed your team not to complete the
10	A. Well, what is yeah, what is	10	report that had been written since July of
11	showing here, yeah, it is. But, you know, as	11	2017 because of the sensitive impurity, that
12	far as whether Mr. Du, you know, actually	12	was because you understood that that would
13	said that or, I don't know, maybe that's a	13	disrupt the marketing of the product which
14	translational error. I really cannot tell.	14	was very profitable to ZHP, and you didn't
15	I mean, you know, it would be best, you know,	15	want to get in the way of that by disclosing
16	to verify with Mr. Jun Du.	16	the NDMA impurity, correct?
17	BY MR. SLATER:	17	MR. BALL: Objection.
18	Q. Do you see what I just read?	18	Foundation, mischaracterizes his
19	A. Yeah, I saw what you read,	19	earlier testimony.
20	yeah.	20	A. What you said really, you know,
21	Q. And with regard to the subject	21	twisted, you know, you know, the fact, okay.
22	of cost and the cost in connection with the	22	Like I said yesterday, that particular
23	process change, in fact, as stated by Mr. Du,	23	impurity is not NDMA, okay. That particular
24	who is one of the top executives in the	24	impurity, you know, was the N-nitroso
	Page 444		Page 446
1	company, this cost reduction from the zinc	1	derivative of irbesartan.
2	chloride process allowed ZHP to dominate the	2	And also, again, that impurity
3	world market share for valsartan. That's	3	was only present, you know, during the, you
4	what, according to this document from the		
5	mian according to this accomment hom the	4	know, process, you know, you know, you know,
	FDA, is what he told the FDA, correct?	4 5	know, process, you know, you know, you know, trial tried to overcome some of the safety,
6	FDA, is what he told the FDA, correct?	5	trial tried to overcome some of the safety,
6 7	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay,	5	trial tried to overcome some of the safety, you know, you know, concern, right.
7	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope.	5 6 7	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you
7 8	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my	5 6 7 8	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity
7 8 9	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely	5 6 7 8 9	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and
7 8 9 10	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you	5 6 7 8 9 10	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know,
7 8 9 10 11	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him	5 6 7 8 9 10 11	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time,
7 8 9 10 11 12	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really	5 6 7 8 9 10 11 12	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you
7 8 9 10 11 12 13	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really said that or really he meant that, you know.	5 6 7 8 9 10 11 12 13	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you know. I didn't say, you know, you know
7 8 9 10 11 12 13 14	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really said that or really he meant that, you know. It could have been, you know, there's some	5 6 7 8 9 10 11 12 13 14	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you know. I didn't say, you know, you know you know, I mean, you can see, you know, you
7 8 9 10 11 12 13 14 15	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really said that or really he meant that, you know. It could have been, you know, there's some misunderstanding.	5 6 7 8 9 10 11 12 13 14 15	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you know. I didn't say, you know, you know you know, I mean, you can see, you know, you know, from such a long period of time, you
7 8 9 10 11 12 13 14 15 16	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really said that or really he meant that, you know. It could have been, you know, there's some misunderstanding. BY MR. SLATER:	5 6 7 8 9 10 11 12 13 14 15 16	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you know. I didn't say, you know, you know you know, I mean, you can see, you know, you know, from such a long period of time, you know, you know, you know, that work has been, you know,
7 8 9 10 11 12 13 14 15 16	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really said that or really he meant that, you know. It could have been, you know, there's some misunderstanding. BY MR. SLATER: Q. And, in fact, the reason why	5 6 7 8 9 10 11 12 13 14 15 16 17	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you know. I didn't say, you know, you know you know, I mean, you can see, you know, you know, from such a long period of time, you know, you know, that work has been, you know, you know, has been ongoing.
7 8 9 10 11 12 13 14 15 16 17	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really said that or really he meant that, you know. It could have been, you know, there's some misunderstanding. BY MR. SLATER: Q. And, in fact, the reason why you and the others who received that e-mail	5 6 7 8 9 10 11 12 13 14 15 16 17 18	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you know. I didn't say, you know, you know you know, I mean, you can see, you know, you know, from such a long period of time, you know, you know, that work has been, you know, you know, has been ongoing. You know, as I explained
7 8 9 10 11 12 13 14 15 16 17 18	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really said that or really he meant that, you know. It could have been, you know, there's some misunderstanding. BY MR. SLATER: Q. And, in fact, the reason why you and the others who received that e-mail in July 2017 from Jinsheng Lin did nothing in	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you know. I didn't say, you know, you know you know, I mean, you can see, you know, you know, from such a long period of time, you know, you know, that work has been, you know, you know, has been ongoing. You know, as I explained yesterday, you know, the reason, you know, I
7 8 9 10 11 12 13 14 15 16 17 18 19 20	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really said that or really he meant that, you know. It could have been, you know, there's some misunderstanding. BY MR. SLATER: Q. And, in fact, the reason why you and the others who received that e-mail in July 2017 from Jinsheng Lin did nothing in response to that, knowing that NDMA was	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you know. I didn't say, you know, you know you know, I mean, you can see, you know, you know, from such a long period of time, you know, you know, that work has been, you know, you know, has been ongoing. You know, as I explained yesterday, you know, the reason, you know, I advised him not to issue is try to avoid
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really said that or really he meant that, you know. It could have been, you know, there's some misunderstanding. BY MR. SLATER: Q. And, in fact, the reason why you and the others who received that e-mail in July 2017 from Jinsheng Lin did nothing in response to that, knowing that NDMA was developing in the valsartan, was because the	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you know. I didn't say, you know, you know you know, I mean, you can see, you know, you know, from such a long period of time, you know, you know, that work has been, you know, you know, has been ongoing. You know, as I explained yesterday, you know, the reason, you know, I advised him not to issue is try to avoid confusion, you know.
7 8 9 10 11 12 13 14 15 16 17 18 19 20	FDA, is what he told the FDA, correct? MR. BALL: Objection. Hearsay, outside the scope. A. Yeah, I think it's outside my scope. I mean, this is, you know, purely you know, I'm a technical person, so, you know, best again, you know, check with him and make sure, you know, or whether he really said that or really he meant that, you know. It could have been, you know, there's some misunderstanding. BY MR. SLATER: Q. And, in fact, the reason why you and the others who received that e-mail in July 2017 from Jinsheng Lin did nothing in response to that, knowing that NDMA was	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	trial tried to overcome some of the safety, you know, you know, concern, right. So as I indicated before, you know, that impurity was not a real impurity in a, you know, real commercial batch, and so and also I indicated to you, you know, you know, the work has been done at the time, you know, the report was already there, you know. I didn't say, you know, you know you know, I mean, you can see, you know, you know, from such a long period of time, you know, you know, that work has been, you know, you know, has been ongoing. You know, as I explained yesterday, you know, the reason, you know, I advised him not to issue is try to avoid

24 correct?

24 told Mr. Lin not to issue that report was to

1 avoid confusion, when last night you told me 2 that you didn't even remember it ever happening. Have you suddenly remembered? 3

> Well, I --Α.

4

5

6

7

3

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14

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19

MR. BALL: Objection.

Mischaracterizes his earlier

testimony, and argumentative.

8 Yeah, I mean, I think what I

said yesterday is, first of all, I just said, 9 you know, you know, I don't remember, you

know, you know, you know, whether, you know, 11

12 you know, I don't remember the details of

13 that conversation, okay?

Second -- second point is I 14

15 said retrospectively, you know, you know, if 16 I want to give you a reasonable explanation.

17 you know, that's -- you know, that could be.

18 you know, the most likely reason, okay.

19 BY MR. SLATER:

20 So do you remember the Jinsheng

21 Lin e-mail and then directing your team not

22 to issue the report?

23 A. I don't remember --24

MR. BALL: Hold on.

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Objection. Vague, compound, 1 2 foundation.

Go ahead.

Α. I don't remember, you know, you

know, that particular e-mail, as I said, 5

because, you know, you know, I receive, you

know, a lot of e-mail every day, and, you 7

know -- so I, you know, basically completely 8

9 slipped through. 10

But with regard to that 11 conversation, you know, you know, I already 12 provide you, you know, the explanation.

13 BY MR. SLATER:

Well, is your explanation based 15 on what you remember, or is your explanation 15 something that you're just coming up with now 16 because you don't remember? 17

MR. BALL: Objection.

Argumentative. And compound.

20 I think, you know, I, you know,

21 I've been quite clear, you know, yesterday 22 and also just moments ago. You know, as I

said, first of all, with regard to that

24 conversation, I do not remember the details

Page 447 Page 449 of the conversation, okay, and then I'm

trying to provide a reasonable explanations.

BY MR. SLATER:

4 Q. When you say you tried to provide reasonable explanations, are you 5

making up these explanations, or are these 6

actually the facts of what you recall 7

8 happened?

9

10

11

MR. BALL: Objection.

Argumentative, and compound, and mischaracterizes his testimony.

12 So, you know, basically, you

13 know, as I said, you know, I just try to, you

know, because I do not remember the details,

15 so as I said this would be a likely, you

16 know, reason, okay?

17 BY MR. SLATER:

18 We talked last night about the

19 fact that we can't find that report. Can you 20 tell me any more than you told me last night

about where we might find that report that 21

you told your team not to issue in April of 22

23 2018? Because we'd really like to read it.

24 MR. BALL: Objection.

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1 Mischaracterizes his testimony.

2 Go ahead and answer if you can.

3 The report should be somewhere,

but I don't know exactly, you know, or at

least, you know, at that time, but I don't

know what would have happened, you know, to

7 it now.

17

8 BY MR. SLATER:

9 Q. Well, it should be in your

10 custodial file because it was provided to you

to read and decide what you wanted to do with 11

it, and after you reviewed it you said not to 12

issue it. So actually we should have gotten 13

it from your custodial file, right?

MR. BALL: Objection.

Speculative, and foundation.

I really don't know whether it

should be there or not. I mean --18

BY MR. SLATER: 19

20 Well, when somebody sends you a

21 completed report to approve, you then have it

in your e-mails and you have it on your 22

computer, it should be there if somebody 23

24 produces everything that's on there that's

	PageID	<u>: 82</u>	157
	Page 451		Page 453
1	relevant, right?	1	sometimes people provided you hard copy
2	MR. BALL: Objection.	2	documents. Did I misunderstand?
3	Speculative.	3	MR. BALL: Objection.
4	A. I mean, at a certain point, you	4	Mischaracterizes his testimony.
5	know, it's possible, you know, yeah, he sent	5	A. But I don't keep that, you
6	that, you know, he might e-mail me, it's	6	know, hard copy. He might okay. He
7	possible. And also it's possible, you know,	7	may he might or he might not. But, you
8	he might just bring a hard copy.	8	know, hypothetically, you know, if he, you
9	But as I said, you know, I just	9	know, bring a hard copy for discussion
10	have no memory, you know, on the detail, what	10	usually, you know, I don't keep them.
11	exactly happened.	11	Otherwise, you know, I'll be, you know, you
12	BY MR. SLATER:	12	know, overwhelmed, you know. I don't like to
13	Q. Did you speak to anybody today	13	have too many, you know, you know, hard copy,
14	other than your lawyers	14	you know, because it's also waste of
15	A. No.	15	resources.
16	Q. Let me just ask you.	16	BY MR. SLATER:
17	Did you speak to anybody today	17	Q. You have some paper documents
18	other than your lawyers	18	in your office; you're not saying you have
19	A. Today	19	none, are you?
20	Q. You've got to let me finish the	20	A. I have some, yeah, like
21	question.	21	company, you know, you know, policies, you
22	MR. BALL: Min, let him finish,	22	know, for some of the company policy. For
23	okay?	23	example, like travel policies, you know, it's
24	THE WITNESS: Okay. Sure.	24	just for easy references.
<u> </u>	<u> </u>		· · · · · · · · · · · · · · · · · · ·
1	Page 452 Mm-hmm.	1	Q. As part of the root cause
2	BY MR. SLATER:	2	investigation conducted by ZHP, did ZHP
3	Q. Did you speak to anybody today	3	review the July 27, 2017 e-mail that we
4	other than your lawyers about this deposition	4	talked about and we've been discussing for
5	or anything that you testified to or were	5	Mr. Lin? Did was that looked at as part
6	asked about yesterday?	6	of ZHP's root cause investigation?
7	A. No.	7	A. You mean was that, or was his
8		8	e-mail being looked at it?
9	,	9	Q. Right. Was that looked at as
10	rephase. I just want to be very clear.	10	part of the root cause investigation
11	Do you recall your computer actually being	11	conducted by ZHP?
12	collected so that information on the computer	12	A. I mean, as I told you, you
13	•	13	
14	could be taken down and provided to us as	14	know, yesterday, you know, you know, it
	part of this litigation? Do you recall that		basically you know, that e-mail didn't,
15	actually happening?	15	you know, you know, generate any resonance
16			MR. BALL: Min, that's a yes or
16	A. Oh, yeah, mm-hmm.	16	
17	A. Oh, yeah, mm-hmm.Q. Do you have hard copy documents	17	no question. Did you was it did
17 18	A. Oh, yeah, mm-hmm. Q. Do you have hard copy documents in your office?	17 18	no question. Did you was it did anybody look at it as part of the root
17 18 19	A. Oh, yeah, mm-hmm. Q. Do you have hard copy documents in your office? A. No.	17 18 19	no question. Did you was it did anybody look at it as part of the root cause analysis?
17 18 19 20	A. Oh, yeah, mm-hmm. Q. Do you have hard copy documents in your office? A. No. MR. BALL: Objection. Vague.	17 18 19 20	no question. Did you was it did anybody look at it as part of the root cause analysis? A. No.
17 18 19 20 21	A. Oh, yeah, mm-hmm. Q. Do you have hard copy documents in your office? A. No. MR. BALL: Objection. Vague. BY MR. SLATER:	17 18 19 20 21	no question. Did you was it did anybody look at it as part of the root cause analysis? A. No. BY MR. SLATER:
17 18 19 20 21 22	A. Oh, yeah, mm-hmm. Q. Do you have hard copy documents in your office? A. No. MR. BALL: Objection. Vague. BY MR. SLATER: Q. Well, you just told me that	17 18 19 20 21 22	no question. Did you was it did anybody look at it as part of the root cause analysis? A. No. BY MR. SLATER: Q. Did anybody speak to Mr. Lin as
17 18 19 20 21	A. Oh, yeah, mm-hmm. Q. Do you have hard copy documents in your office? A. No. MR. BALL: Objection. Vague. BY MR. SLATER:	17 18 19 20 21	no question. Did you was it did anybody look at it as part of the root cause analysis? A. No. BY MR. SLATER:

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	Page 455		Page 457
1	Did anybody speak to Jinsheng	1	MR. BALL: Objection.
2	Lin as part of the root cause investigation?	2	Speculation.
3	A. I have no idea.	3	A. You know, as I said, you know,
4	Q. Certainly Mr. Lin should have	4	at this point, you know, I just cannot answer
5	that report on his computer, right?	5	that question.
6	MR. BALL: Objection.	6	BY MR. SLATER:
7	Speculation.	7	Q. Why can't you answer that
8	A. He may, you know, right now,	8	question?
9	may or may not. I really don't know.	9	A. Because, you know, anything can
10	BY MR. SLATER:	10	happen between then and now.
11	Q. Somebody should have that	11	Q. What do you mean by that,
12	report on their computer, right?	12	"anything can happen"?
13	MR. BALL: Objection.	13	A. You know, it just could be
14	Speculation.	14	deleted or, you know, you know, for whatever
15	BY MR. SLATER:	15	the reason, if it's, you know, saved
16	_		· · · · · · · · · · · · · · · · · · ·
	Q. It should exist somewhere	16	somewhere at some point.
17	within it should rephrase.	17	MR. SLATER: Cheryll, let's go
18	That report should exist	18	to Exhibit 209, please.
19	somewhere within ZHP, right?	19	MR. BALL: Adam, did we lose
20	MR. BALL: Objection.	20	Cheryll? There we go. Okay.
21	Speculation and argumentative and	21	MR. SLATER: I don't think we
22	compound.	22	would lose her. She would just say,
23	A. A more accurate statement would	23	You know what? It's late enough, I've
24	be, you know, it most likely this document	24	had it with you people, and I'm moving
	Page 456		Page 458
1	may be present in the computer, you know, at	1	on. Wouldn't be the first time she's
2	a certain point of time. But as far as its	2	done that to me.
3	current status, I really, you know, have	3	MS. CALDERON: Won't be the
4	no I do not have that knowledge.	4	last.
5	BY MR. SLATER:	5	MR. SLATER: Excellent. I hope
6	Q. Well, does ZHP have that	6	you got that on the record.
7	knowledge?	7	MR. BALL: Yeah, we're still on
8	MR. BALL: Objection.	8	the record.
9	Speculation.	9	MR. SLATER: Good, good.
10	BY MR. SLATER:	10	BY MR. SLATER:
11	Q. Remember, you're speaking for	11	Q. Looking now at ZHP-209
12	ZHP, so I'm asking	12	rephrase.
13	MR. BALL: No, I understand,	13	Looking now at Exhibit 209,
14	Adam, I didn't tell him not to answer.		
15		14	this is an "IARC Monograph on the Evaluation
	MR. SLATER: No, no. I was	15	of the Carcinogenic Risk of Chemicals to
16	going to rephrase the question to make	16	Humans."
17	it clearer.	17	MR. SLATER: And if you could
18	BY MR. SLATER:	18	scroll up a little more, Cheryll,
19	Q. Speaking for ZHP, that report	19	please.
20	should exist somewhere, right	20	Q. It's addressing some N-nitroso
21	MR. BALL: Objection.	21	compounds.
22	BY MR. SLATER:	22	Do you see that?
23	Q in the company, and be able	23	A. Mm-hmm.
24	to be produced to us, right?	24	MR. SLATER: And just to

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	Page 459		Page 461
1	scroll up again to be sure that we're	1	of NDMA, you know, was also under the acidic,
2	clear on timing. I just want to get	2	you know, pH.
3	to the very bottom of the page to get	3	So, yes, so from that
			·
4	to the date.	4	perspective, yeah, they are consistent.
5	Q. And the date on this document	5	BY MR. SLATER:
6	is May 1978.	6	Q. And this is an IARC monograph
7	Do you see that?	7	from 1978. It's certainly something that
8	A. Mm-hmm.	8	scientists would be aware of and have
9	Q. You know what IARC is, right?	9	available to them if they wanted to consult
10	A. Oh, yes.	10	it, correct?
11	Q. It's the International Agency	11	A. Yes.
12	for Research on Cancer, a respected	12	MR. BALL: Objection.
	•		•
13	organization, correct?	13	Speculative, and calls for expert
14	A. Oh, yes.	14	testimony.
15	MR. BALL: Objection.	15	BY MR. SLATER:
16	Speculation.	16	Q. And it would have been
17	BY MR. SLATER:	17	available to be reviewed in 2011 certainly,
18	Q. Speaking for ZHP with regard	18	right, since it's dated in 1978, correct?
19	to rephrase.	19	A. I'm sorry, what?
20	Speaking for ZHP, the IARC is	20	MR. BALL: Go ahead, answer.
21	certainly a respected organization, correct?	21	THE WITNESS: Okay.
22	A. Yes.	22	Yeah, basically, you know, if
23	MR. SLATER: Let's look now at	23	there is a particular, you know, you
24	page 36, and I want to look at the	24	know, reason, you know, at the time,
2-7	page 60, and I want to look at the		Know, reason, you know, at the time,
	· •		·
	Page 460		Page 462
1	Page 460 third paragraph.	1	Page 462 yeah, someone will, you know, you
1 2		1 2	_
	third paragraph.		yeah, someone will, you know, you
2	third paragraph. Q. The third rephrase.	2	yeah, someone will, you know, you know, going and trying to find this document.
2 3	third paragraph. Q. The third rephrase. The third paragraph on page 36 starts out, "It has been known since 1865	2	yeah, someone will, you know, you know, going and trying to find this document. MR. SLATER: Let's go, Cheryll,
2 3 4 5	third paragraph. Q. The third rephrase. The third paragraph on page 36 starts out, "It has been known since 1865 that the reaction of dimethylamine	2 3 4 5	yeah, someone will, you know, you know, going and trying to find this document. MR. SLATER: Let's go, Cheryll, to page 40, please. Thank you.
2 3 4 5 6	third paragraph. Q. The third rephrase. The third paragraph on page 36 starts out, "It has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrite at an	2 3 4 5 6	yeah, someone will, you know, you know, going and trying to find this document. MR. SLATER: Let's go, Cheryll, to page 40, please. Thank you. BY MR. SLATER:
2 3 4 5 6 7	third paragraph. Q. The third rephrase. The third paragraph on page 36 starts out, "It has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrite at an acidic pH yields" N-nitro sodium	2 3 4 5 6 7	yeah, someone will, you know, you know, going and trying to find this document. MR. SLATER: Let's go, Cheryll, to page 40, please. Thank you. BY MR. SLATER: Q. Looking at page 40, the first
2 3 4 5 6 7 8	third paragraph. Q. The third rephrase. The third paragraph on page 36 starts out, "It has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrite at an acidic pH yields" N-nitro sodium methylene" I'm going to start over.	2 3 4 5 6 7 8	yeah, someone will, you know, you know, going and trying to find this document. MR. SLATER: Let's go, Cheryll, to page 40, please. Thank you. BY MR. SLATER: Q. Looking at page 40, the first full paragraph, the second sentence starts
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2 3 4 5 6 7 8 9	third paragraph. Q. The third rephrase. The third paragraph on page 36 starts out, "It has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrite at an acidic pH yields" N-nitro sodium methylene" I'm going to start over. The third paragraph on page 36 starts out stating, "It has been known since	2 3 4 5 6 7 8 9	yeah, someone will, you know, you know, going and trying to find this document. MR. SLATER: Let's go, Cheryll, to page 40, please. Thank you. BY MR. SLATER: Q. Looking at page 40, the first full paragraph, the second sentence starts out, "The principal techniques employed for the analysis of volatile N-nitrosamines have
2 3 4 5 6 7 8 9 10 11	third paragraph. Q. The third rephrase. The third paragraph on page 36 starts out, "It has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrite at an acidic pH yields" N-nitro sodium methylene" I'm going to start over. The third paragraph on page 36 starts out stating, "It has been known since 1865 that the reaction of dimethylamine	2 3 4 5 6 7 8 9 10 11	yeah, someone will, you know, you know, going and trying to find this document. MR. SLATER: Let's go, Cheryll, to page 40, please. Thank you. BY MR. SLATER: Q. Looking at page 40, the first full paragraph, the second sentence starts out, "The principal techniques employed for the analysis of volatile N-nitrosamines have been described in a recent publication," and
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	third paragraph. Q. The third rephrase. The third paragraph on page 36 starts out, "It has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrite at an acidic pH yields" N-nitro sodium methylene" I'm going to start over. The third paragraph on page 36 starts out stating, "It has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrite at an acidic pH yields NDMA." Do you see that? A. Yes. Q. And, again, that's describing what happened in the zinc chloride process, correct? MR. BALL: Objection. Foundation. A. This you know, I think the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	yeah, someone will, you know, you know, going and trying to find this document. MR. SLATER: Let's go, Cheryll, to page 40, please. Thank you. BY MR. SLATER: Q. Looking at page 40, the first full paragraph, the second sentence starts out, "The principal techniques employed for the analysis of volatile N-nitrosamines have been described in a recent publication," and it gives a citation from 1978. Do you see that? A. Right. MR. BALL: Hold on. Adam, I don't see it. Where are you? MR. SLATER: I'm in the paragraph MR. BALL: Oh, I see it. I'm sorry. I'm sorry. I was looking farther down.

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	Page 463		Page 465
1	relative merits of high- and low-resolution	1	MR. BALL: You both were
2	mass spectrometry are discussed, since use of	2	talking at the same time. I didn't
3	mass spectrometry as a confirmatory technique	3	hear the question. I'm sorry.
4	is particularly important."	4	A. So, Adam, could you repeat
5	Do you see what I just read?	5	the you know, the question, right, Rick
6	A. Yes.	6	wanted to hear, right?
7	Q. And certainly it was	7	BY MR. SLATER:
8	well-known, at least as of 1978 when this	8	Q. When this talks about volatile
9	IARC monograph was published, that mass	9	N-nitrosamines, that would include NDMA,
10	spectrometry was an important confirmatory	10	correct?
11	technique to identify nitrosamines such as	11	A. Yes.
12	NDMA, correct?	12	MR. SLATER: All right. Let's
13	MR. BALL: Objection.	13	take this document down, and we're
14	Speculative, and calls for expert	14	going to switch to another document.
15	testimony.	15	So I don't know I lost track
16	A. This description itself is very	16	of time, so you tell me.
17	vague, okay. Between, you know, that time	17	MR. BALL: We're at three hours
18	and now, you know, mass spectrometry has made	18	and 26 minutes, so we can it's
19	quite, you know, a significant progress.	19	really up to you, Adam. We've got
		20	about an hour six since the last
20	So without knowing, you know,	21	break.
21	the detail what this particular, you know,	22	
22	you know, sentence is referring, you know,		MR. SLATER: All right. Let's
23	it's very difficult, you know, you know, to	23	keep going. I'm fine
24	assess, you know.	24	MR. BALL: Do you think you can
	Page 464	١.,	Page 466
1	I mean, one thing I would say,	1	finish your next document in like the
2	you know, based upon, you know, such a low	2	last the next 15 minutes, or do we
3	level, right, now these, you know, you know,	3	want to take a break now, or
4	like 30 ppb, you know, or sometimes even	4	MR. SLATER: I don't think I'm
5	lower, I would say that the technology or the	5	going to finish this in the next
6	mass spectrometry, you know, during that time	6	15 minutes. I've got a lot of
7	would not be adequate to analyze or detect at	7	interaction documents here.
8	such a low level, you know, as we see or need	8	MR. BALL: Okay. So why don't
9	to, you know, test today.	9	we take a break, you can get yourself
10	 Q. You would agree with me that at 	10	set up and then, you know, if we need
11	least as of 1978 when this IARC monograph was	11	to take another break we can, if we
12	published, it was known that mass	12	don't we won't, okay?
13	spectrometry was an important confirmatory	13	MR. SLATER: That sounds good.
14	technique to identify nitrosamines such as	14	All right. So let's take ten.
15	NDMA, correct?	15	THE VIDEOGRAPHER: The time
16	MR. BALL: Objection. Calls	16	right now is 11:07 a.m. We're now off
17	for expert testimony.	17	the record.
18	A. Here it just said, yeah, the	18	(Whereupon, a recess was
19	principal technique, yeah, for the analysis	19	taken.)
20	of volatile N-nitrosamine.	20	THE VIDEOGRAPHER: The time
21	(Cross-talking.)	21	right now is 11:22 a.m. We're back on
	· · · · · · · · · · · · · · · · · · ·	22	the record.
22	BY MR. SLATER.	1//	
22	BY MR. SLATER. Q. That would include NDMA.		
22 23 24	Q. That would include NDMA, correct?	23 24	BY MR. SLATER: Q. Looking now at rephrase.

Page 467 Page 469 1 Going back to the ICH cancer with regard to N-nitrosamine, you 2 Guideline, M7 from 2013, we're now looking at know, is really related to or referring to, 3 Section 7.2.1 titled "Mutagenic Impurities you know, you know, the -- in animals. 4 With Positive Carcinogenicity Data (Class 1 BY MR. SLATER: 5 in Table 1)." And for these -- rephrase, I'm 5 This standard is talking about Q. going to start over. 6 impurities in pharmaceuticals. Those would 6 be pharmaceuticals that would be taken by 7 MR. SLATER: Let me just check 7 8 something. I might want to go to a human beings, correct? different page. 9 9 Α. Yes. You know what, let's go to 10 And with regard to humans 10 Q. page 10, to the top of the page. taking pharmaceuticals, this is talking about 11 11 12 Great. I'll start over. certain impurities that display extremely 12 high carcinogenic potency. That's the 13 Q. We're back -- rephrase. 13 Looking at the ICH guideline context, correct? 14 14 MR. BALL: Objection. Vague, 15 from 2013, we're now on page 10. At the top 15 of page 10 it states, "A disproportionately calls for expert testimony. 16 17 high number of members of some structural With regard to that, you know, 17 18 classes of mutagens, i.e. aflatoxin-like-, 18 specific, you know, the three classes, yes. 19 N-nitroso-, and azoxy structures, of which BY MR. SLATER: 19 20 some may occur as impurities in 20 And then when it says, Q. 21 pharmaceuticals, display extremely high 21 "Acceptable intakes for these high-potency 22 carcinogenic potency. Acceptable intakes for carcinogens would likely be significantly 22 23 these high-potency carcinogens would likely lower than the acceptable intakes defined in 23 24 be significantly lower than the acceptable 24 this guideline," this is talking about the Page 468 Page 470 intakes defined in this guideline." need to evaluate the specific impurities and Do you see what I just read? 2 determine what would be the acceptable level 3 A. Yes. 3 for that impurity as opposed to using the 4 And first of all, they're Q. threshold approach, correct? 5 talking about these structures displaying 5 MR. BALL: Objection. 6 extremely high carcinogenic potency. That 6 Foundation. 7 would relate to the tendency to be able to Yeah. I'm sorry. Yes. 7 8 increase your risk for or cause cancer, BY MR. SLATER: 8 9 correct? 9 And in this case, in 2018 the 10 MR. BALL: Objection. Vague. FDA actually established certain limits when Specifically with regard to 11 11 this became known to them that there was NDMA 12 nitrosamine, so I think in previous, you 12 in the valsartan, correct? 13 know, you know, conversations, you know, I 13 MR. BALL: Objection. 14 think I indicated the carcinogenicity, it is 14 Foundation. 15 being discussed here, is referring to, you 15 A. Yeah, that was issued by FDA, 16 know, the result, or the data derived from 16 yeah, in 2018. 17 animal studies. 17 BY MR. SLATER: 18 BY MR. SLATER: 18 Q. And those limits for NDMA were 19 Q. When this refers to extremely 19 96 nanograms, which would equate to 0.3 parts 20 high carcinogenic potency, that's talking per million, correct? 20 about the ability to cause or increase the 21 21 A. There was no such limit at that 22 risk for cancer, correct? 22 time. That limit was established only after, 23 MR. BALL: Objection. Vague. 23 you know, the events of June 2018.

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Again, the risk, you know, to

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In 2018, after the FDA was made

1 aware that there was NDMA in the valsartan, 2 the FDA established certain limits, correct? 3 A. Yes. And also i indicates of the yesterday at different time point, you know, 4 yesterday at different time point, you know, 5 you know, the limits also, you know, changes 6 with time. From the very beginning of it 7 should be absent, meaning for NDMA would be 5 8 ppb in terms of the limit of detection to the 9 current, you know, 95 enangaran, which is 90 equivalent to 300 ppb. So - so you can see 1 there is a 60 times of increase in terms of 1 the allowable intake. 10 equivalent to 300 ppb. So - so you can see 1 there is a 60 times of increase in terms of 1 the allowable intake. 11 date for NDMA manufactured using the 1 the allowable intake. 12 Dest-change process (2 cinc chloride 1 process). Provide the corresponding GC 1 the allowable intake. 13 Q. The FDA established limits of 1 G. For NDMA in valsartan, correct? 15 million, correct? 16 million, correct? 17 Q. For NDMA in valsartan, correct? 18 A. Versus its maximum dose, yes. 20 Q. And for NDEA, actually 19 process) are provided in Table 1.* 21 Destablished limits of 26.5 nanograms or 20 Q. And for NDEA, actually 19 process) are provided in Table 1.* 22 MR. BALL: Objection. 23 Foundation. 24 A. Yash, it looks like, yes. 25 Page 472 26 MR. BALL: Objection. 27 Speculation. 28 Page 472 29 MR. BALL: Cobjection. 29 MR. BALL: Cobjection. 30 A. A sthe title of this M7 all implies, you know, the purpose is limit of 4 potential carcinogenic risk. 31 MR. SLATER: Cheryll, what I'd 16 like to do now is pull up, if we could, the purpose is limit of 4 potential carcinogenic risk. 42 Mr. SLATER: Cheryll, what I'd 16 like to do now is pull up, if we could. Exhibit 42. The now do is turn. A manufactured or becember 28, 2011, which was one of the validation batches, the 11 miltion and divided 76 by .3 to ty to figure out how many times the FDA limit. A port of the power of the provision batches, the 11 miltion and divided 76 by .3 to ty to figure out how many times the FDA limi		PageID	: 82	162
2 the FDA established certain limits, correct? 4 yesterday at different time point, you know, 5 you know, the limits also, you know, 5 you know, the limits also, you know, 6 you know, the limits also, you know, 6 you know, 96-nanogram, by beginning of it 7 should be absent, meaning for NDMA would be 5 8 ppb in terms of the limit of detection to the 9 current, you know, 96-nanogram, which is 10 equivalent to 300 ppb. So - so you can see 11 there is a 60 times of increase in terms of 12 the allowable intake. 13 Q. The FDA established limits of 14 96 nanograms, which equates to 0.3 parts per 15 million, correct? 16 MR. SLATER: 17 Q. For NDMA in valisartan, correct? 18 A. Versus its maximum dose, yes. 19 Q. And for NDEA, actually 20 established limits of 26.5 nanograms or 21 .083 parts per million, correct? 21 .083 parts per million, correct? 22 MR. BALL: Objection. 23 Foundation. 24 A. Yeah, it looks like, yes. 26 MR. SLATER: 27 Q. And these limits were set as 28 rephrase. 29 MR. BALL: Objection. 29 MR. BALL: Objection. 20 MR. BALL: Objection. 20 MR. BALL: Objection. 21 A. As the title of 22 MR. BALL: Calls for expert 23 for protect patient safety, correct? 24 MR. SLATER: 25 MR. BALL: Calls for expert 26 MR. BALL: Calls for expert 27 O. Page 42 is a document dated 28 September 1st, 2018 titled "Response to DMF 1 information Request Letter." 29 Do you see that there? 20 A. Morhmmn. Yep. 21 Does that sound right to you?		Page 471		Page 473
3 A. Yes. And also I indicated 4 yesterday at different time point, you know, 5 you know, the limits also, you know, changes 6 with time. From the very beginning of it 7 should be absent, meaning for NDMA would be 5 8 ppb in terms of the limit of detection to the 9 current, you know, 96-nanogram, which is 10 equivalent to 300 ppb. So — so you can see 11 there is a 60 times of increase in terms of 11 there is a 60 times of increase in terms of 12 the allowable intake. 13 Q. The FDA established limits of 14 96 nanograms, which equates to 0.3 parts per 15 million, correct? 16 A. Yes, for valsartan. 17 Q. For NDMA in valsartan, correct? 18 A. Versus its maximum dose, yes. 19 Q. And for NDEA, actually 19 established limits of 26.5 nanograms or 20 established limits of 26.5 nanograms or 21 .083 parts per million, correct? 22 MR. BALL: Objection. 23 Foundation. 24 A. Yesh, it looks like, yes. 25 Q. And these limits were set as — 26 rephrase. 27 Q. And these limits were set in order 28 to protect patient safety, correct? 29 MR. BALL: Objection. 20 A. A st he title of — 21 MR. BALL: Calls for expert 21 Lestimony. 22 A. As the title of — 23 MR. BALL: Calls for expert 24 A. Sa the title of - 25 MR. BALL: Chipection. 26 MR. BALL: Chipection. 27 Speculation. 28 A. As the title of — 29 MR. BALL: Chipection. 30 A. A st he title of this M7 31 implies, you know, the purpose is limit of protect patient safety, correct? 4 MR. SLATER: Cheryll, what I'd 4 Iske to do now is pull up, if we could, Exhibit 42. 4 These limits were set in order 5 to protect patient safety, correct? 5 MR. BALL: Chipection. 6 MR. BALL: Chipection. 7 MR. BALL: Objection. 8 A. As the title of this M7 8 MR. BALL: Chipection. 9 MR. BALL: Chipection. 19 MR. BALL: Chipection. 10 MR. BALL: Objection. 10 MR. BALL: Objection. 10 MR. BALL: Objection. 11 A. The set imit to fore the form of the top. Interest the form of the top. Thank you. 12 MR. BALL: Objection. 13 MR. BALL: Objection. 14 MR. BALL: Objection. 15 MR. BALL: Objection. 16 MR. BALL: Objection. 17 MR. BAL	1	aware that there was NDMA in the valsartan,	1	to page 8, if we could, please.
4 yesterday at different time point, you know, 5 you know, the limits also, you know, changes 6 with time. From the very beginning of it 7 should be absent, meaning for NDMA would be 5 ppb in terms of the limit of detection to the 9 current, you know, 96-nanogram, which is 10 equivalent to 300 ppb. So - so you can see 1 the 10 there is a 60 times of increase in terms of 12 the allowable intake. 13 Q. The FDA established limits of 14 96 nanograms, which equates to 0.3 parts per 15 million, correct? 15 million, correct? 16 A. Yes, for valsartan. 17 Q. For NDMA in valsartan, correct? 18 A. Versus its maximum dose, yes. 18 post-change process (2 process) are provided in Table 1.* 20 post-change process (2 process) are provided in Table 1.* 20 post-change process (2 process) are provided in Table 1.* 21 post-change process (2 process) are provided in Table 1.* 22 post-change process (2 process) are provided in Table 1.* 23 about the limits. 24 process (2 process) are provided in Table 1.* 24 process (2 process) are provided in Table 1.* 25 process (2 process) are provided in Table 1.* 26 process (2 process) are provided in Table 1.* 27 provide a summary of the data for all lots tested to 12 process). Provide the corresponding GC 14 chromatograms.* 15 process (2 process) 2 process (2	2	the FDA established certain limits, correct?	2	MR. SLATER: If you could,
5 you know, the limits also, you know, changes 6 with time. From the very beginning of it 7 should be absent, meaning for NDMA would be 5 8 ppb in terms of the limit of detection to the 9 current, you know, 96-nanogram, which is 10 equivalent to 300 ppb. So so you can see 11 there is a 60 times of increase in terms of 11 there is a 60 times of increase in terms of 11 there is a 60 times of increase in terms of 12 the allowable intake. 13 Q. The FDA established limits of 14 96 nanograms, which equates to 0.3 parts per 15 million, correct? 16 A. Yes, for valsartan. 17 Q. For NDMA in valsartan, correct? 18 A. Versus its maximum dose, yes. 19 Q. And for NDEA, actually 19 established limits of 26.5 nanograms or 20 assibalished limits of 26.5 nanograms or 21 .083 parts per million, correct? 22 MR. BALL: Objection. 23 Foundation. 24 A. Yeah, it looks like, yes. Page 472 1 BY MR. SLATER: 2 Q. And these limits were set as 3 rephrase. 3 rephrase. 4 These limits were set in order 5 to protect patient safety, correct? 5 MR. BALL: Calls for expert 10 testimony. 11 Go ahead. 12 A. As the title of 9 MR. BALL: Calls for expert 13 implies, you know, the purpose is limit of 14 potential carcinogenic risk. 15 MR. SLATER: 16 Q. Page 42 is a document dated 17 oy ou see that there? 18 Q. Page 42 is a document dated 18 document, there was a request, you can see at 19 document, there was a request, you can see at 19 the color, little letter 'b.', "Provide a summary of the data for all lots tested to 10 date for NDMA manufactured using the 11 date for NDMA manufactured using the 12 post-change process (2inc chloride 13 process). Provide the corresponding GC 14 date for NDMA manufactured using the 16 summary of the data for all lots tested to 17 date for NDMA manufactured using the 18 summary of the data for all lots tested to 18 summary of the data for all lots tested to 19 poyess). Provide the corresponding GC 19 process?). Provide the corresponding GC 19 poyes that there 10 o. And repulse the time the provided in the time t	3	A. Yes. And also I indicated	3	Cheryll, just scroll up a little bit
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7 Should be absent, meaning for NDMA would be 5 8 ppb in terms of the limit of detection to the 9 current, you know, 96-ananogram, which is 10 equivalent to 300 ppb. So - so you can see at 11 the allowable intake. 12 the allowable intake. 12 post-change process (2 nic chloride 13 or NDMA manufactured using the 14 96 ananograms, which equates to 0.3 parts per 15 million, correct? 16 A. Yes, for valsartan. 16 A. Yes, for valsartan. 17 Q. For NDMA in valsartan, correct? 18 A. Versus its maximum dose, yes. 19 or Say parts per million, correct? 19 osas parts per million, correct? 21 o.083 parts per million, correct? 22 MR. BALL: Objection. 23 Foundation. 24 A. Yeah, it looks like, yes. 24 These limits were set as 3 rephrase. 4 These limits were set in order 15 to protect patient safety, correct? 5 MR. BALL: Objection. 25 MR. BALL: Objection. 26 MR. BALL: Objection. 27 Speculation. 28 A. As the title of this M7 Speculation. 29 MR. BALL: Calls for expert 10 testimony. 19 MR. BALL: Calls for expert 10 potential carcinogenic risk. 10 MR. SLATER: Cheryll, what I'd 16 like to do now is pull up, if we could, Exhibit 42. 10 po you see that there? 20 Do you see that there? 21 Do you see that there? 22 A. Mm-hmm. Yep. 20 Do you see that there? 22 Do you see that there? 23 A. Mm-hmm. Yep. 20 Do you see that there? 24 Do you see that there? 25 Do you see that there? 26 Do you see that there? 27 Do you see that there? 28 Do you see that there? 27 Do you see that there? 28 Do you see that there? 29 Do you see that there? 20 Do you see that there? 21 Do you see that there? 21 Do you see that there? 21 Do you see that there? 22 Do you see that there? 23 Do you see that there? 24 Do you see that there? 25 Do you see that there? 25 Do you see that there? 25 Do you see that there? 26 Do you see that there? 26 Do you see that there? 27 Do you see that th	6	with time. From the very beginning of it	6	we read the top. Thank you.
8 ppb in terms of the limit of detection to the 10 equivalent to 300 ppb. Sos oy ouc an see 11 there is a 60 times of increase in terms of 12 the allowable intake. 13 Q. The FDA established limits of 14 96 nanograms, which equates to 0.3 parts per 15 million, correct? 16 A. Yes, for valsartan. 17 Q. For NDMA in valsartan, correct? 18 A. Versus its maximum dose, yes. 19 Q. And for NDEA, actually 19 process) are provided in Table 1." 20 established limits of 25.5 nanograms or 21 .083 parts per million, correct? 22 MR. BALL: Objection. 23 For NDMA in valsartan. 24 A. Yeah, it looks like, yes. 25 MR. SLATER: 26 Q. And these limits were set as 27 a R. A sthe title of 28 MR. BALL: Calls for expert 29 to protect patient safety, correct? 40 MR. BALL: Calls for expert 41 testimony. 41 Go ahead. 42 A. As the title of this M7 43 implies, you can see at 9 the top, little letter "b.", "Provide a 10 the top, little letter "b.", "Provide an 10 the top, little letter "b.", "Provide an 10 the top, little letter "b.", "Provide an 10 the data for all lots tested to 10 the porcess'). Provide the corresponding GC 14 def or NDMA manufactured using the porcess'). Provide the corresponding GC 15 A. Versus its maximum dose, yes. 16 Summary of the data for all lots tested to 12 the porcess'). Provide the corresponding GC 16 A. Yes, for valsartan. 17 date for NDMA manufactured using the post-change process ('the corresponding GC 17 date for NDMA manufactured using the post-change process'). Provide an 4 the post-change process ('the corresponding GC 18 A. Versus its maximum dose, yes. 18 poy us now the data for all lots tested to 12 provided in Table 1." 19 Do you see that the "process" are provided in Table 1." 20 Do you show the table at this point. A little more. Thank you. 21 little more. Thank you. 22 A. A. As the title of 23 fall little letter "b.", "	7		7	•
9 current, you know, 96-nanogram, which is 10 equivalent to 300 ppb. Soso you can see 11 there is a 60 times of increase in terms of 12 the allowable intake. 13 Q. The FDA established limits of 14 96 nanograms, which equates to 0.3 parts per 15 million, correct? 16 A. Yes, for valsartan. 17 Q. For NDMA in valsartan, correct? 18 A. Versus its maximum dose, yes. 19 Q. And for NDEA, actually 19 established limits of 26.5 nanograms or 20 established limits of 25.5 nanograms or 21 .083 parts per million, correct? 22 MR. BALL: Objection. 23 Foundation. 24 A. Yeah, it looks like, yes. 24 Page 472 1 BY MR. SLATER: 2 Q. And these limits were set as 3 rephrase. 3 These limits were set in order 5 to protect patient safety, correct? 6 MR. BALL: Cobjection. 7 Speculation. 8 A. As the title of 9 MR. BALL: Calls for expert 10 testimony. 11 Go ahead. 12 A. As the title of this M7 13 implies, you know, the purpose is limit of 14 potential carcinogenic risk. 15 MR. SLATER: 16 Q. Page 42 is a document dated 17 C. Page 42 is a document dated 18 September 1st, 2018 titled "Response to DMF 21 linformation Request Letter." 20 Do you see that there? 21 Do you see that there? 22 Do you see that there? 23 A. Mm-hmm. Yep. 24 the top, little letter "b.", "Provide a lous unmany of the data for all lots tested to corrects ("cinc chloride potenses") crocess). Provide the corresponding GC 25 provide the corresponding GC 26 potential correct? 27 And the Response is that, "The summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all lots tested to summany of the data for all ots tested to summany of	8	ppb in terms of the limit of detection to the	8	document, there was a request, you can see at
10 equivalent to 300 ppb. So so you can see 11 there is a 60 times of increase in terms of 11 there is a 60 times of increase in terms of 11 there is a 60 times of increase in terms of 12 the allowable intake. 13 Q. The FDA established limits of 14 96 nanograms, which equates to 0.3 parts per 15 million, correct? 16 A. Yes, for valsartan. 16 a. Versus its maximum dose, yes. 17 Q. For NDMA in valsartan, correct? 18 A. Versus its maximum dose, yes. 19 Q. And for NDEA, actually 20 established limits of 26.5 nanograms or 21 .083 parts per million, correct? 22 MR. BALL: Objection. 23 Foundation. 24 A. Yeah, it looks like, yes. Page 472 1 BY MR. SLATER: 2 Q. And these limits were set as 3 rephrase. 4 These limits were set in order 2 to protect patient safety, correct? 6 MR. BALL: Objection. 7 Speculation. 7 Speculation. 8 A. As the title of 9 MR. BALL: Calls for expert 10 testimony. 11 Go ahead. 12 a little, Cheryll, so that we just show the table at this point. A little more. Thank you. 4 Q. We talked a few moments ago 5 about the limits the FDA set, and for NDMA it was manufactured on December 28, 2011, which was one of the validation batches, the 17 could, Exhibit 42. 18 BY MR. SLATER: 18 BY MR. SLATER: 19 Q. Page 42 is a document dated 20 September 1st, 2018 titled "Response to DMF 20 and divided 76 by .3 to try to figure out how many times the FDA limit. 17 could, Exhibit 42. 28 Do you see that there? 29 Do you see that there? 20 Dosy use that there? 21 Dosy use that there? 22 Dosy use that there? 23 A. Mm-hmm. Yep. 24 Drovide the corresponding CC 25 drovide the corresponding CC 26 drovide 76 by .3 to try to figure out how many times the FDA limit. 29 Dosy use that there? 20 Dosy use that there? 21 Dosy and the Response to DMF 20 and divided 76 by .3 to try to figure out how many times the FDA limit. 29 Dosy and the mists of .12 process (21 process) grace provided in Table 1." 29 Dosy and the manufactured using the corresporate of the validation batches, the purpose is limit of to 25 times the FDA limi	9		9	the top, little letter "b.", "Provide a
there is a 60 times of increase in terms of 12 the allowable intake. 12 post-change process (2rinc chloride 2 post-change process). Provide the corresponding GC 14 96 nanograms, which equates to 0.3 parts per 15 million, correct? 15 And the Response is that, "The 16 A. Yes, for valsartan. 16 summary of the data for all lots tested to 17 date for NDMA manufactured using the 18 A. Versus its maximum dose, yes. 18 post-change process (the zinc chloride 2 process) are provided in Table 1." 19 post-change process (the zinc chloride 2 process) are provided in Table 1." 19 poy ou see that? 20 established limits of 26.5 nanograms or 20 poy ou see that? 21 Oa3 parts per million, correct? 21 A. Mrn-hmm, yes. 22 A. Yeah, it looks like, yes. 24 MR. SLATER: You can scroll up 25 about the limits. 24 MR. SLATER: You can scroll up 26 A. Yeah, it looks like, yes. 27 Page 472 a little, Cheryll, so that we just show the table at this point. A little more. Thankyou. 2 A. A st he title of - 2 A. As the title of this M7 a limplies, you know, the purpose is limit of 25 potential carcinogenic risk. 25 MR. SLATER: Cheryll, what I'd like to do now is pull up, if we could, Exhibit 42. 26 A. Mrn-hmm. Yep. 27 A. Mrn-hmm. Yep. 28 September 1st, 2018 titled "Response to DMF 20 Looking now at Batch Number 1, and divided 76 by .3 to try to figure out how many times the FDA limit. 20 Dose that sound right to you?	10	equivalent to 300 ppb. So so you can see	10	summary of the data for all lots tested to
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27 S. VVIICE TO HOW GO IS LUTT 24 A. PTODADIY, YEATI.	24	Q. What I'd like to now do is turn	24	A. Probably, yeah.

PageID: 82163 Page 475 Page 477 1 Q. And just randomly looking at for patients, those levels of NDMA are not this, going on the right-hand column, 2 acceptable from a health standpoint, correct? Batch 409 at 99.6, that's 332 times the FDA MR. BALL: Objection. Calls 3 4 limit. 4 for expert testimony. 5 Do you see that? 5 As I indicated yesterday, in 6 MR. BALL: Adam, I don't see terms of the health risks, you know, it would 6 7 be better suited, you know, to be answered by batch 409. 8 MR. SLATER: It's in the second a toxicologist. 9 BY MR. SLATER: 9 column. 10 Well, speaking for ZHP, those 10 Right here, yeah. Q. MR. BALL: Oh, number 409, not 11 levels are certainly not acceptable for sale, 11 12 batch 409. The batch number is --12 correct? okay. I misunderstood what you were 13 MR. BALL: Objection. Vague. 13 At the time of the -- you know, 14 14 pointing to, Adam. Α. 15 MR. SLATER: No problem, no 15 of the registration, you know, you know, prior to these events, you know, this 16 problem. 16 17 Cheryll, could you scroll down 17 particular specification was not there, you 18 know, so all product met all the, you know, 18 a little bit, please? Let's scroll a few pages down to page 11 of 33, to 19 regulatory filed specifications. So this is 19 the top of that chart. You'll see 20 really a retrospective analysis. 20 BY MR. SLATER: 21 it's -- you're going to see number 125 21 22 in the left and 517 in the middle. 22 Q. Well. let's talk 23 There you are. 23 retrospectively. 24 Looking now at the batch 24 Retrospectively looking at Q. Page 476 Page 478 1 numbered 518, we have 188.1 parts per 1 these levels, it was never acceptable to be 2 million, which if you divide that by .3, 2 selling valsartan with these levels of NDMA, 3 that's 627 times the limit set by the FDA. 3 correct? From a health perspective from 4 ZHP's view of the health risk? 4 correct? MR. BALL: Objection. 5 Α. Yes. 5 6 Q. And we can go through this. My 6 Speculative and compound, and calls point being, this actually was through --7 for expert testimony. 8 rephrase. 8 BY MR. SLATER: 9 9 Q. I'll ask the question again. MR. SLATER: Cheryll, can you 10 scroll to the end on page 16, just so One second. 10 we can establish the number of batches From ZHP's perspective, the 11 11 health risk posed by these levels of NDMA was 12 that were tested? Perfect. 12 never acceptable, correct? 13 783 batches. We can agree that Q.

14

15

16

17

20

18 toxicologist.

19 BY MR. SLATER:

all of these batches tested at numbers many,

many times more than the limit the FDA ended 15

up setting, correct? 16

MR. BALL: Objection. Vague.

They're all higher, yeah, than 18 Α.

19 0.3.

17

24

20 BY MR. SLATER:

21 Q. And in terms of the health and 22 safety component, those levels certainly

23 are -- rephrase.

In terms of health and safety

22 topic, and you would agree with me on behalf 23 of ZHP these levels would never have been and

Q. Well, I'm asking you, who is

21 testifying for ZHP in this deposition on this

MR. BALL: Objection. Vague.

potential risk to, you know, patients, again,

You know, again, you know, with

this would be best answered by a

24 never were acceptable from a health

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	Page 479		Page 481
1	perspective for the patients using	1	risk or to you know, to essentially,
2	medication, correct?	2	you know, it's a potential risk, okay. So a
3	MR. BALL: Objection. Calls	3	potential risk is not a confirmed link.
4	for expert testimony, vague.	4	BY MR. SLATER:
5	A. Again, you know, it's not	5	Q. You would agree with me that
6	for you know, for me, you know, to, you	6	the people who took the valsartan
7	know, give that evaluations.	7	contaminated with NDMA have a higher risk to
8	BY MR. SLATER:	8	develop cancer than if they had not taken the
9	Q. Well, the FDA certainly has	9	valsartan contaminated with NDMA.
10	toxicologists on their staff, right?	10	You would agree with that
11	A. Oh, yeah.	11	statement, correct?
12	Q. And they determined these	12	MR. BALL: Objection. Outside
13	levels would not be acceptable from a health	13	the scope, and calls for expert
14	standpoint, correct?	14	testimony, and foundation.
15	MR. BALL: Objection.	15	A. Again, it's best to be answered
16	Speculative.	16	by a toxicologist.
17	A. Retrospectively, based on the	17	BY MR. SLATER:
18	current knowledge, this is the case.	18	Q. This is Topic 36. This is what
19	Retrospectively, again.	19	you're designated to testify on. It's not
20	BY MR. SLATER:		,
1		20	expert testimony, it's not beyond the scope.
21	Q. And that unacceptable health	21	It's ZHP's evaluation and knowledge of the
22	risk is an unacceptable risk that somebody	22	health risks of this contamination with NDMA.
23	could develop cancer as a result of using	23	MR. BALL: Adam, I didn't
24	this medication contaminated with NDMA at	24	instruct him not to answer.
	Page 480		Page 482
1	these levels, correct?	1	MR. SLATER: No, I understand,
2	MR. BALL: Objection. Calls	2	but what I'm
3		_	
1	for expert testimony, compound,	3	MR. BALL: Adam, I've made my
4	foundation.	4	objection.
1			· · · · · · · · · · · · · · · · · · ·
4	foundation. A. As I indicated yesterday, you know, NDMA, you know, to human is a probable	4 5 6	objection. MR. SLATER: The problem is your witness continues to say he won't
4 5	foundation. A. As I indicated yesterday, you	4 5	objection. MR. SLATER: The problem is your witness continues to say he won't answer the question when he's
4 5 6	foundation. A. As I indicated yesterday, you know, NDMA, you know, to human is a probable or potential carcinogenic. So whether, you know, these levels will cause cancer in	4 5 6 7 8	objection. MR. SLATER: The problem is your witness continues to say he won't answer the question when he's designated to answer the question.
4 5 6 7	foundation. A. As I indicated yesterday, you know, NDMA, you know, to human is a probable or potential carcinogenic. So whether, you	4 5 6 7	objection. MR. SLATER: The problem is your witness continues to say he won't answer the question when he's
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4 5 6 7 8 9	foundation. A. As I indicated yesterday, you know, NDMA, you know, to human is a probable or potential carcinogenic. So whether, you know, these levels will cause cancer in humans is not confirmed.	4 5 6 7 8 9	objection. MR. SLATER: The problem is your witness continues to say he won't answer the question when he's designated to answer the question. MR. BALL: No, no. I don't
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PageID: 82165 Page 483 Page 485 1 You know, I -- and again, you 1 A. This is what, you know, you know, this result, you know, indicated that 2 said, okay? I didn't say that, okay. And there is no increased, you know, cancer risk 3 from, you know, ZHP's perspective in terms of 4 the health risk, right, all I can tell you 4 to patients taking ranitidine versus, you 5 know, the patient taking, you know, 5 based on my expertise, based on my 6 famotidine. 6 understanding, is this is a potential risk to 7 Q. You told me earlier that ZHP 7 human, okay. Anything beyond that, you know, 8 it's really not appropriate for me, you know, made the decision to stop selling its valsartan because of the levels of NDMA in to comment. 9 10 the valsartan. That was for the benefit of BY MR. SLATER: 10 patients, right? 11 11 Well, you're the only person designated on this topic, so you're the 12 MR. BALL: Objection. 12 Mischaracterizes his earlier person I have to ask these questions of. 13 13 14 testimony. MR. BALL: Objection. 14 Argumentative. 15 Α. Yeah, I think I already give 15 16 the answer, you know, previously. 16 A. Yeah, you know, I give you BY MR. SLATER: answer, you know, you know. You know, my 17 17 Well, let me ask you now. 18 answer, you know, or, you know, by 18 Q. 19 representing ZHP is at this point our, you 19 When ZHP decided to stop selling -- rephrase. 20 20 know, you know, risk assessment, you know, 21 As you said that -- rephrase. 21 based upon, you know, you know, you know, you 22 When ZHP, as you said, decided 22 know, the potential risk, you know, to human. to stop selling the valsartan contaminated 23 23 You know, everything, you know, is out there, with NDMA, that decision was made based on 24 24 you know, as I said. Page 486 Page 484 At this point it's still a 1 the health risk to patients, right? 2 potential risk, okay. There is no 2 MR. BALL: Objection. 3 established link, okay? 3 Mischaracterizes his earlier 4 And also yesterday, you know, I 4 testimony. 5 gave you an example, right, a 40,000-plus, 5 I said based upon the potential 6 you know, patient taking ranitidine, you risk to human, yeah, or to patient. 7 know, which is known now, you know, to give 7 BY MR. SLATER: 8 huge amount. You know, the level of NDMA 8 When you say due to the 9 actually, if you look at the paper, actually 9 potential risk to patients, it was determined 10 are much higher, you know, than these. And by ZHP that it was unacceptably dangerous for 11 versus a group of control, you know, a group patients to take the pills contaminated with 11 12 like more than 10,000, you know, patient 12 the NDMA, correct?

13 taking famotidine, which is the same class of 14 the medication, but would not decompose to 15 give NDMA. 16 So, as I indicated, you know, 17 this is from my, you know, limited, you know, understanding, you know, in this particular, 19 you know, like a clinical side, right, you 20 know.

21 To me this is very 22 well-controlled, with large enough population 23 to have a significant, you know, you know, 24 meaningful, you know, results.

13 MR. BALL: Objection. 14 Mischaracterizes his earlier 15 testimony. Again, this is what you're 16 Α. saying. Okay. This is not what I said. So 18 I think I have answered numerous times, you know, yesterday as well as today. 19 20 BY MR. SLATER: 21 Q. Well, when you say that it was 22 a potential risk, what you're saying is that 23 it was too dangerous, otherwise you would 24 have kept selling it, correct?

	PageiD	. 82	100
	Page 487		Page 489
1	MR. BALL: Objection.	1	Potential Impurities in Valsartan.
2	Mischaracterizes his testimony, and	2	Do you see that?
3	argumentative.	3	A. Oh, yeah, mm-hmm, sure.
4	A. I think any anyone with a,	4	MR. SLATER: And, Cheryll, if
5	you know, a reasonable, you know,	5	you could scroll down through that
6	understanding will not equal a potential	6	list of impurities, let's go through
7	risk, you know, to, like you said, a very	7	the lettered ones. Go to the last
8	dangerous. These these two are clearly,	8	lettered one that we can get to. I
9	you know, you know, they are mean	9	think it's probably going to be J.
10	different things.	10	There we go.
11	BY MR. SLATER:	11	Q. In the list of impurities in
12	Q. When you say a potential risk,	12	this DMF, it goes up to impurity J.
13	it was an unacceptable risk in ZHP's	13	Impurity K, which we've discussed previously,
14	viewpoint, and that's why ZHP stopped selling	14	was not listed, correct?
15	the valsartan, correct?	15	A. Based upon this table, it was
16	MR. BALL: Objection.	16	not listed in there.
17	Mischaracterizes his testimony.	17	Q. And rephrase. And please
18	A. Again, our decision was based	18	well, rephrase.
19	upon the potential risk, you know, to	19	And I think you've told us
20	patients.	20	already that by this time ZHP knew that there
21	BY MR. SLATER:	21	was impurity K in the valsartan? Do I
22	Q. And the decision that that	22	understand that correctly?
23	potential risk was unacceptable, correct?	23	A. I have not saying, you know,
24	MR. BALL: Objection.	24	specifically like by 2013, you know, we knew,
	•		
1	Page 488	1	Page 490
1 2	Page 488 Mischaracterizes his testimony, asked	1 2	you know, the presence of impurity K or
2	Page 488 Mischaracterizes his testimony, asked and answered.	2	you know, the presence of impurity K or whatever. So I think that this is a
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Mischaracterizes his testimony, asked and answered. A. I mean, I you know, if you want to keep asking the same question, you know, you know, I can give you the same answer. You know, basically as I said, the decision was made based upon the potential risks to patients and which, you know, that potential risk is based upon, you know, the available scientific, you know, you know, documents available, you know, as of today. MR. SLATER: Take this document down. And Cheryll, let's go to Exhibit 205, please. BY MR. SLATER: Q. This is the DMF amendment that was filed it's dated November 10, 2013 was filed in December of 2013. Do you see that?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	you know, the presence of impurity K or whatever. So I think that this is a regulatory filing document, so I think my colleague from the regulatory affair, you know, will have a much better, you know, you know, answer to you. Q. Well, the regulatory affairs people aren't the ones determining what impurities are in the substance, they seek that advice from people like yourself, right? MR. BALL: Objection. Vague. A. Well, basically, you know, they will, you know, get you know, confirm the results from R&D people, including, you know, my organizations. But here, yeah, I clearly don't see impurity K. You know, the very reason at this point why it's not in there, you know, I just cannot tell you the details, because I don't know, you know, those details. Only thing that I know is

	PageID	<u>. 82</u>	.167
	Page 491		Page 493
1	BY MR. SLATER:	1	underneath that table, it says, "Regarding
2	Q. You don't know when that was?	2	the impurity D-J and hydrolysis product,
3	A. I would say it's looks like,	3	there is not any high potency genotoxic
4	you know, it's probably, you know, maybe	4	group, such as, aflatoxin-like-, N-nitroso-,
5	after this one, you know.	5	and azoxy-compound has been included in these
6	Q. Do you have any idea when it	6	impurities."
7	was discovered or who discovered it?	7	I want to stop there.
8	MR. BALL: Objection. Vague.	8	We know certainly in retrospect
9	MR. SLATER: All right. I'll	9	that, in fact, there was NDMA in the
10	ask it again.	10	valsartan, correct?
11	BY MR. SLATER:	11	A. Yes, retrospective.
12	Q. Do you have any idea who	12	Q. So this DMF was inaccurate when
13	identified impurity K, and when that occurred	13	it said there were no N-nitroso compounds,
14	in the valsartan manufactured by ZHP?	14	correct?
15	A. I told you yesterday	15	A. It was based upon the knowledge
16	retrospectively that we knew it was, you	16	at the time.
17	know, it was, you know, discovered by the	17	Q. It was incorrect at the time,
18	original innovator, you know, Novartis.	18	correct?
19	MR. SLATER: Let's scroll	19	
			A. As I said, retrospectively it
20	through, slowly through the end of the	20	turned out to be not accurate.
21	list of impurities, please.	21	MR. SLATER: I think we can
22	Q. And please look at this because	22	take that down. And the next document
23	I'm going to ask you at the end	23	that we're going to go to is
24	MR. SLATER: Stop for one	24	ZHP01567728. And I think you can put
	Page 492		Page 494
1	second, Cheryll.	1	the English translation into the
2	Q. Tell me if you see any	2	the link or whatever it is, Cheryll,
3	nitrosamines listed as potential impurities.	3	if you could do that as well, please.
4	MR. SLATER: And you can		And then ence it's there you
5		4	And then once it's there you
6	continue scrolling.	5	all can let me know and I'll continue.
0	Q. You would agree with me that no	5 6	
7		5 6 7	all can let me know and I'll continue.
	Q. You would agree with me that no	5 6	all can let me know and I'll continue. MS. CALDERON: Can I take
7	Q. You would agree with me that no nitrosamines were listed as potential	5 6 7	all can let me know and I'll continue. MS. CALDERON: Can I take can we take just a minute off the
7 8	Q. You would agree with me that no nitrosamines were listed as potential impurities for the zinc chloride process valsartan, correct? A. Yes, in this file, yes.	5 6 7 8	all can let me know and I'll continue. MS. CALDERON: Can I take can we take just a minute off the record? I just want to locate the
7 8 9	Q. You would agree with me that no nitrosamines were listed as potential impurities for the zinc chloride process valsartan, correct?	5 6 7 8 9	all can let me know and I'll continue. MS. CALDERON: Can I take can we take just a minute off the record? I just want to locate the English translation.
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7 8 9 10 11 12	Q. You would agree with me that no nitrosamines were listed as potential impurities for the zinc chloride process valsartan, correct? A. Yes, in this file, yes. MR. SLATER: Let's go, if we could, Cheryll, to page 364.	5 6 7 8 9 10 11 12	all can let me know and I'll continue. MS. CALDERON: Can I take can we take just a minute off the record? I just want to locate the English translation. MR. SLATER: Sure. THE VIDEOGRAPHER: Off the record, or timer?
7 8 9 10 11 12 13	Q. You would agree with me that no nitrosamines were listed as potential impurities for the zinc chloride process valsartan, correct? A. Yes, in this file, yes. MR. SLATER: Let's go, if we could, Cheryll, to page 364. Q. Okay. Now we have rephrase.	5 6 7 8 9 10 11 12 13	all can let me know and I'll continue. MS. CALDERON: Can I take can we take just a minute off the record? I just want to locate the English translation. MR. SLATER: Sure. THE VIDEOGRAPHER: Off the record, or timer? MR. BALL: No, it's fine, we
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. You would agree with me that no nitrosamines were listed as potential impurities for the zinc chloride process valsartan, correct? A. Yes, in this file, yes. MR. SLATER: Let's go, if we could, Cheryll, to page 364. Q. Okay. Now we have rephrase. Looking at page 364, there's a listing that says, "All the potential organic impurities are demonstrated in valsartan listed as follows." And you can see there's no impurity K and there's no nitrosamines, correct? A. Yeah, looks like. MR. SLATER: Cheryll, please	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	all can let me know and I'll continue. MS. CALDERON: Can I take can we take just a minute off the record? I just want to locate the English translation. MR. SLATER: Sure. THE VIDEOGRAPHER: Off the record, or timer? MR. BALL: No, it's fine, we can go off the record. THE VIDEOGRAPHER: Time right now is 11:54 a.m. We're now off the record. (Pause.) (Whereupon, Exhibit Number ZHP-313was marked for identification.)
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	PageID	: 82:	168
	Page 495		Page 497
1	MR. SLATER: Great. Thank you.	1	correct?
2	You know, Cheryll, scroll down	2	A. I don't remember, you know, you
3	a little bit just so we can see the	3	know, at the time, you know, when I probably
4	whole bottom e-mail. Perfect. A	4	clicked the link, and so I don't remember
5	little more actually. See if you can	5	exactly who published it. But if you say,
6	get no, too much. There you go.	6	you know, that's Norwegian oh yeah.
7	BY MR. SLATER:	7	Here's the Norwegian. Yeah, I saw that.
8	Q. Looking at Exhibit313, it's an	8	Okay, yeah.
9	e-mail exchange in June 2018, June 16th.	9	MR. SLATER: Let's go now to
10	Do you see that?	10	the next page, please, to Section 2,
11	A. Yeah, mm-hmm.	11	paragraph 2. Perfect.
12	Q. It looks like someone named	12	Q. Looking now at paragraph 2,
13	Minfa Wang wrote to you on June 16, 2018.	13	titled "Evaluation of cancer risk from
14	Who is Minfa Wang?	14	exposure to nitrosamines."
15	A. She is the analytical head at	15	Do you see that?
16	Prinston Pharmaceuticals, which is a	16	A. Oh, yeah, mm-hmm.
17	subsidiary of Huahai.	17	Q. And this says, "Nitrosamines
18	Q. And she wrote to you and said,	18	represent a large and diverse family of
19	"Attached paper is from web below." And ther		synthetic and naturally occurring compounds.
20	she quotes a link, and says, "It looks the	20	Approximately 90 percent of the 300
21	potent is different between" and I assume	21	nitrosamines tested have shown carcinogenic
22	that means potency "is different between	22	effects in bioassays and laboratory animals.
23	nitrosamines and nitramines. Nitramine is	23	Among these, NDMA has been most thoroughly
24	less potent than that nitrosamine. Have been	24	
<u> </u>	·		<u>'</u>
1	Page 496 confirmed as nitrosamine?"	4	Page 498
1 2		1	mutagen and carcinogen." And it cites an NIPH report from 2009, which would be the
3	That's what she asked you, correct?	3	same organization, Norwegian Institute of
4	A. Yes.	4	Public Health.
5	Q. And you then let's scroll up	5	It then says, "Due to their
	·	6	potent carcinogenicity, other health outcomes
6	now to your response.	_	
	And you confirmed "It is	7	of these compounds have been given less
8	confirmed the impurity is NDMA," correct? A. Yes.	8	emphasis and are therefore less well documented."
9		9	
11	MR. SLATER: Can we as	10	So that would have been some
	Exhibit 314, let's put up the next	11	information that would have been available to
12	document, which was the document that	12	you when Minfa Wang wrote to you in
13	that link will take you to.	13	June 2018?
14	THE WITNESS: Right.	14	A. Yeah.
15	(Whereupon, Exhibit Number	15	MR. SLATER: Let me just check
16	ZHP-314was marked for	16	something.
17	identification.)	17	Okay. We're done with that
18	BY MR. SLATER:	18	document.
19	Q. It's titled "Health effects of	19	At this point I'm going to wrap
20	amines and derivatives associated with CO2	20	up for the night.
21	capture: Nitrosamines and nitramines."	21	MR. BALL: Okay. Adam, we've
22	And it looks like it was an	22	gone like four hours tonight. I
23	analysis or study that was carried out by the	23	just I want to make sure you
24	Norwegian Institute of Public Health,	24	understand we're not going to add time

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	Page 499		Page 501
1	on to the last day.	1	INSTRUCTIONS TO WITNESS
2	MR. SLATER: You know what, I	2	
	•		D 1 1 1 12
3	don't want to argue with you, but it's	3	Please read your deposition over
4	fine.	4	carefully and make any necessary corrections.
5	THE VIDEOGRAPHER: Do you want	5	You should state the reason in the
	•		
6	that off the record?	6	appropriate space on the errata sheet for any
7	MR. BALL: Yeah, yeah.	7	corrections that are made.
8	MR. SLATER: It's fine if it's	8	After doing so, please sign the
			· · · · · · · · · · · · · · · · · · ·
9	on the record or off the record.	9	errata sheet and date it. It will be
10	THE VIDEOGRAPHER: The time	10	attached to your deposition.
11	right now is 12:02 p.m. We're now off	11	It is imperative that you return
12	the record.	12	
			the original errata sheet to the deposing
13	(Whereupon, the deposition was	13	attorney within thirty (30) days of receipt
14	adjourned.)	14	of the deposition transcript by you. If you
15	,	15	fail to do so, the deposition transcript may
			•
16		16	be deemed to be accurate and may be used in
17		17	court.
18		18	
19		19	
20		20	
21		21	
22		22	
23		23	
24		24	
	B 500		D 500
	Page 500		Page 502
1	Page 500 CERTIFICATE	1	Page 502
	=		Page 502 ERRATA
1	CERTIFICATE I, MAUREEN O'CONNOR POLLARD, Registered Diplomate	1	
1 2 3	CERTIFICATE I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems	1 2	ERRATA
1 2	CERTIFICATE I, MAUREEN O'CONNOR POLLARD, Registered Diplomate	1 2 3	
1 2 3	CERTIFICATE I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the	1 2	ERRATA
1 2 3 4	CERTIFICATE I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, MIN LI, PhD, was remotely	1 2 3	ERRATA
1 2 3 4 5	CERTIFICATE I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the	1 2 3 4 5	ERRATA PAGE LINE CHANGE REASON:
1 2 3 4 5 6 7	CERTIFICATE I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, MIN LI, PhD, was remotely duly identified and sworn by me to testify to the truth, the whole truth, and nothing but the truth.	1 2 3 4 5 6	ERRATA PAGE LINE CHANGE REASON:
1 2 3 4 5 6	CERTIFICATE I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, MIN LI, PhD, was remotely duly identified and sworn by me to testify to the truth, the whole truth, and nothing but the truth. I DO FURTHER CERTIFY that	1 2 3 4 5 6 7	ERRATA PAGE LINE CHANGE REASON:
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4	I,, do Hereby certify that I have read the foregoing	
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10	Min Li, Ph.D. Date	
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